

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

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John S. Nagy, Reg. No. 30,664



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/693,577  
Applicant : Lilip Lau, Bill Hartigan  
Filed : October 23, 2003  
Art Unit : 3736  
Examiner : Samuel G. Gilbert  
Title : SELF-SIZING CARDIAC HARNESS FOR TREATING  
CONGESTIVE HEART FAILURE

Docket No.: : PARCR 65971  
Customer No. : 24201

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

Dear Sir:

I, DARRELL H. OGI, DECLARE AS FOLLOWS:

1. I am an employee of Paracor Medical, Inc., the Assignee of the present application. I previously worked for Paracor Surgical, Inc., the predecessor of Paracor Medical, Inc., and presently I am Director of Clinical Engineering.

2. I have first-hand knowledge of the facts set forth herein. I declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true.

BEST AVAILABLE COPY



3. Through the instructions of the co-inventors of the present application, Lilip Lau and Bill Hartigan, and with their guidance, I worked on the development of a cardiac harness from a time just before October 8, 1999.

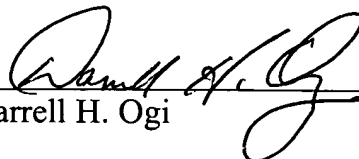
4. Attached hereto as Exhibit A are laboratory notebook pages, in my handwriting, as evidence of the development work that I was instructed to do with respect to the cardiac harness prior to October 8, 1999. The dates have been redacted, however, my signature and the signature of a witness appear on some of the notebook pages. The notebook pages are consecutively numbered and show continuous development work.

5. Attached hereto as Exhibit B are laboratory notebook pages, in my handwriting, as evidence of the development work that I was instructed to do on the cardiac harness after October 8, 1999. The notebook pages are consecutively numbered and show continuous development work. Upon information and belief, I worked on almost a daily basis on the development of the cardiac harness, and periodically made entries in my laboratory notebook relating to the work I had completed.

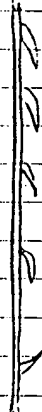
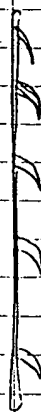
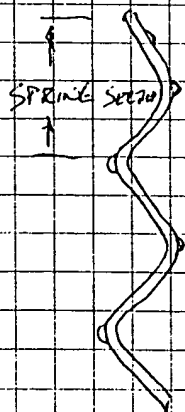
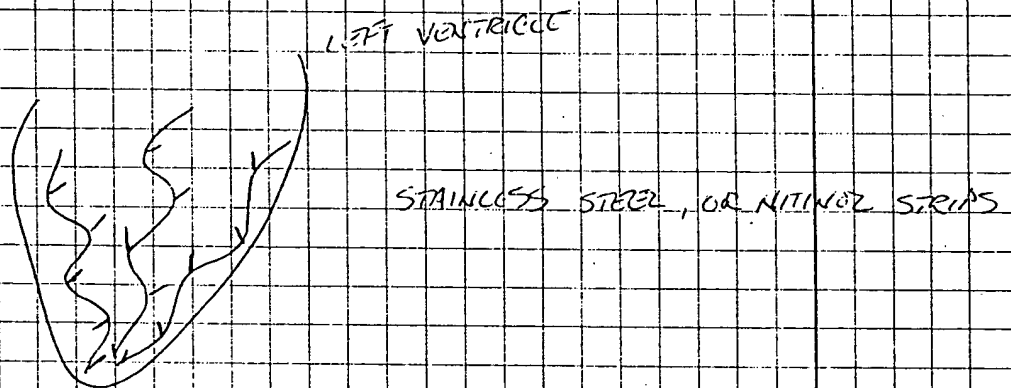
6. All of the development work that I was instructed to do was conducted in the United States at Palo Alto, California.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and I acknowledge that any willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and may jeopardize the validity of the application or patent issuing thereon.

Date: 11/14/05

  
Darrell H. Ogi

METAL STRIPS WITH ANCHORS & SPRING COMPONENT  
 METHOD OF STRAIN RELIEF AND ENHANCED  
 CONTRACTILITY OF MUSCLE TISSUE. INSTEAD  
 OF A BASKET, RUN STRIPS OF SPRINGS  
 ALONG THE INSIDE OF THE VENTRICLE TO  
 REDUCE DISTENSION OF THE WALL AND  
 ASSIST CONTRACTILITY

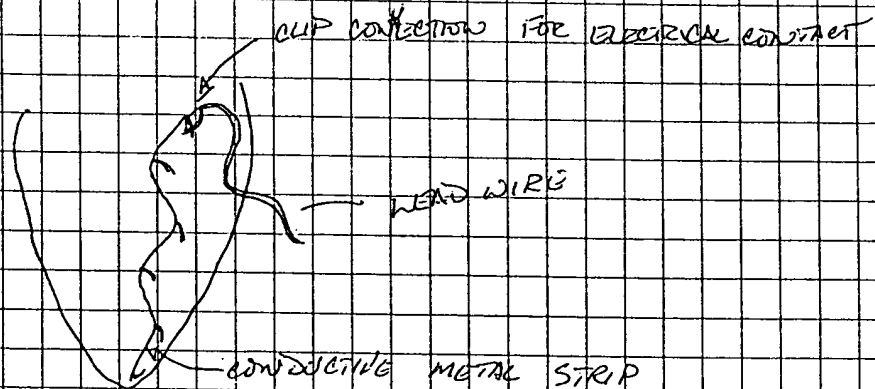


Chen/H/G

READ UNDERSTOOD  
 Mark M. Porter

## METAL STRIPS AS AN ELECTRICAL CONDUCTOR

THE METAL STRIPS USED TO STRAIN RELIEVE THE LEFT VENTRICAL WOULD MOST LIKELY BE MADE OF STAINLESS STEEL, OR NICKEL TITANIUM, BOTH OF WHICH CONDUCT ELECTRICAL CURRENT. POTENTIALLY USE THE METAL STRIPS AND ANCHORS AS AN ELECTRODE TO PACE THE LEFT VENTRICLE. CAN PACE IN CONJUNCTION WITH RIGHT VENTRICULAR, OR RT DUAL CHAMBER PACING. ELECTRICAL CONTACT MAY BE MADE THROUGH THE MYOCARDIUM, OR THROUGH THE SEPTUM.

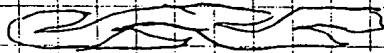


R.H.G.

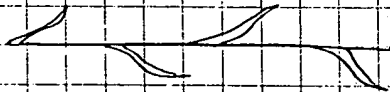
READ & UNDERSTOOD *Blair Pater*



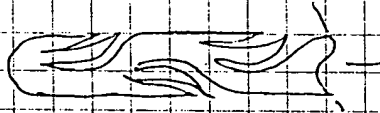
## SHEET METAL ANCHORS



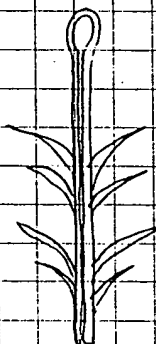
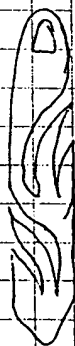
STAINLESS STEEL  
OR N. T.



LOW PROFILE, EASY  
INSERTION INTO TISSUE,  
BUT REASONABLE ANCHORING  
FORCE

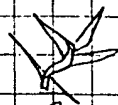


MORE BARBS TO  
CREATE MORE SURFACE  
AREA



DOUBLE LAYERED  
SHEET METAL STRIP  
WITH BARBS IN OPPOSING  
DIRECTION. BASE  
STRIP MAY BE  
TWISTED TO SPREAD  
BARBS CIRCUMFERENTIALLY

*Handwritten signature*



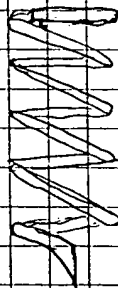
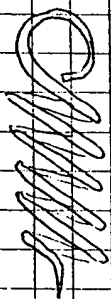
READ & UNDERSTOOD

*Handwritten signature*

## COIL SPRINGS AS ARIBRS

METAL COILS WITH A CONSTANT PITCH  
MAY TAKE MINIMAL FORCE TO INSERT INTO  
TISSUE THAN SHEET METAL BARBS.

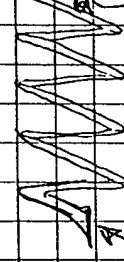
COILS MAY HAVE A SINGLE ENTRY WOUND  
AND TEAR LESS TISSUE IF "SCREENED"  
INTO THE TISSUE LIKE A CORKSCREEN RATHER  
THAN TEARING TISSUE LIKE A BARB MAY  
DO.



DRIVE  
ENGAGEMENT  
FLAT



NEEDLE  
OR  
SOLIDITY



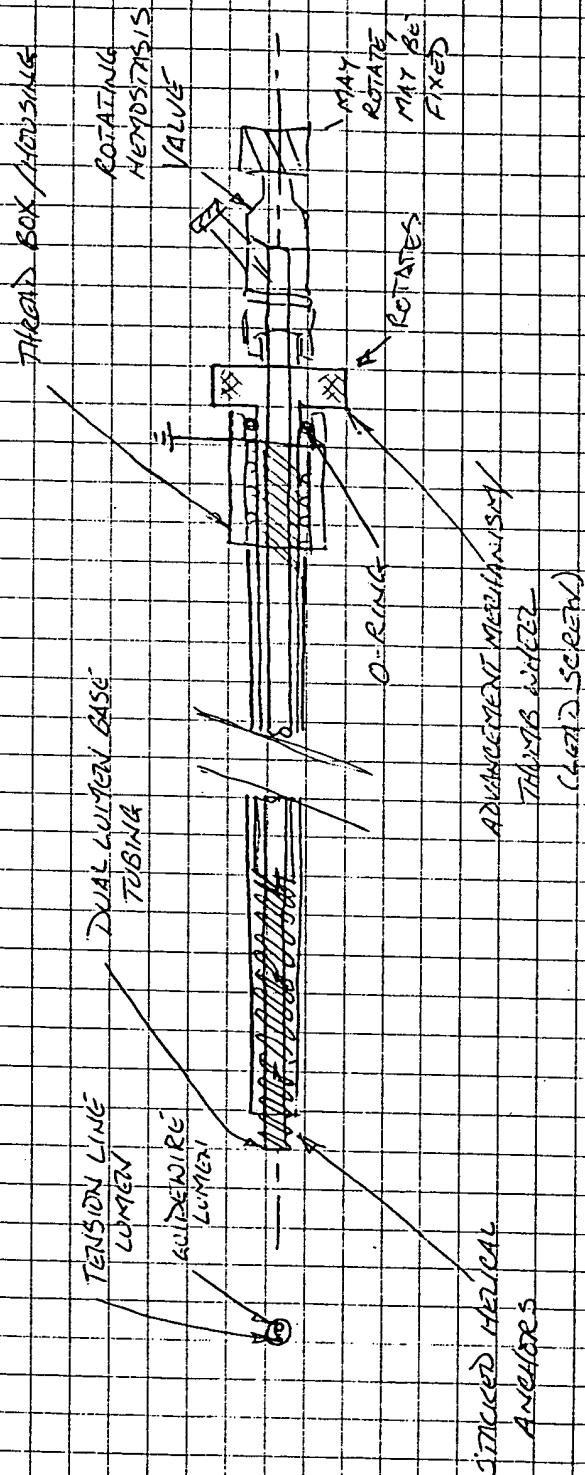
DRIVE  
ENGAGEMENT  
FLAT



David G.

READ + UNDERSTOOD David G.

# DELIVERY CATHETER/DRIVE MECHANISM



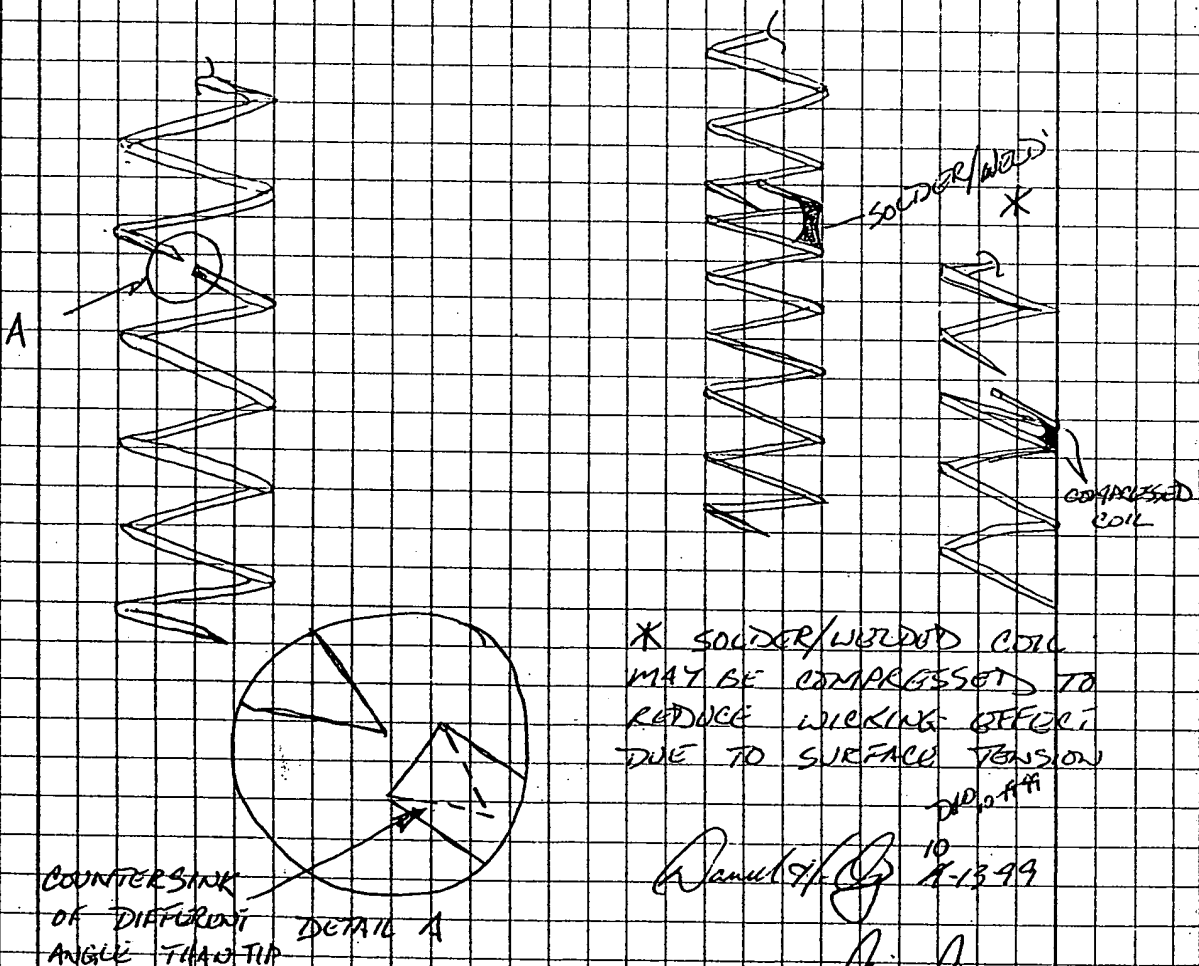
READ & UNDERSTOOD

*David [Signature]*

*David [Signature]*

# COIL SPRING TERMINATIONS

A METHOD WILL BE NEEDED FOR INDIVIDUAL AND/OR SPRINGS/COILS TO BE ABLE TO ENGAGE WITH ONE ANOTHER SUCH THAT TORQUE MAY BE TRANSMITTED FROM ONE COIL TO ANOTHER. WITH SUFFICIENT ENGAGEMENT, MULTIPLE COILS CAN BE LINED UP AND DRIVEN FROM THE PROXIMAL END.



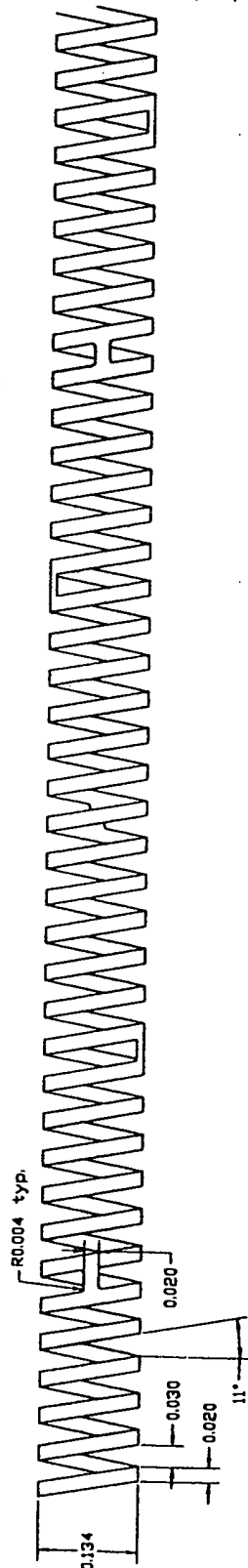
READ & UNDERSTOOD

Done (only 10/17/97)

PATTERN TO LASER CUT COILS FROM TUBING

DWG 10-19-99

10-19-99



PART: HA-1A  
10/13/1999  
LILIP LAU  
(408)730-5218

CONFIDENTIAL

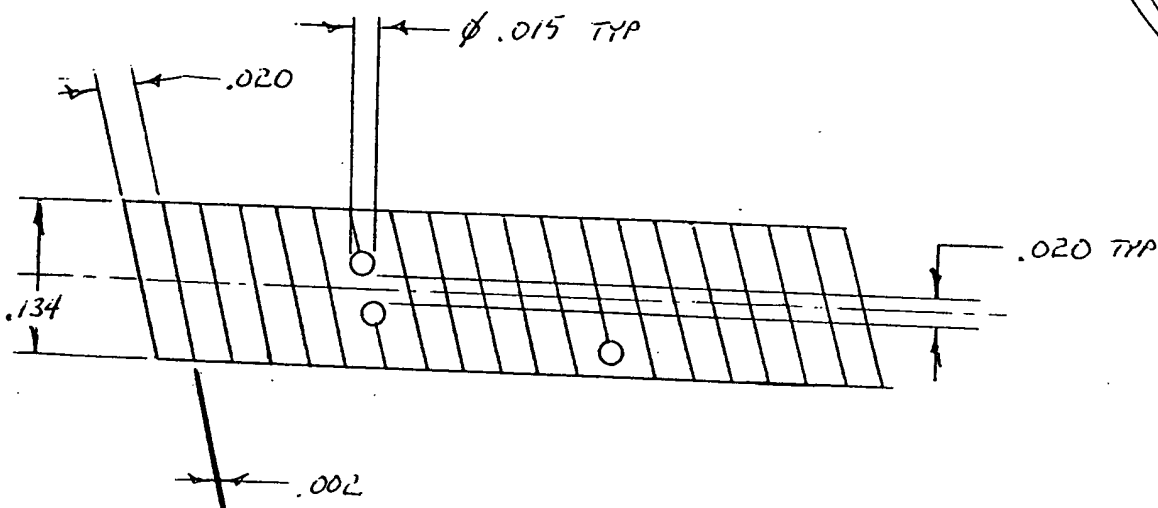
ALL DIMENSIONS IN INCHES

Part to be cut from .106x.134, 304 stainless steel tubing

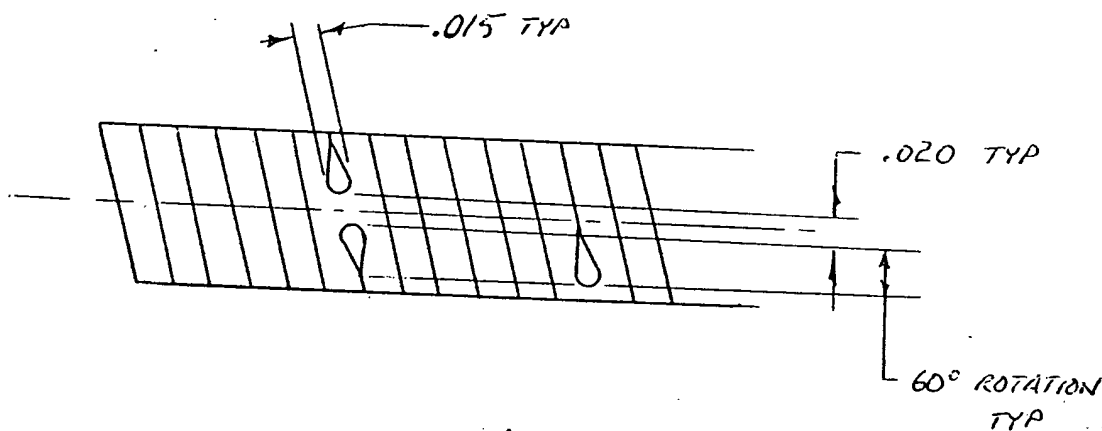
READY UNDERSTOOD: 10/31/99

8

## REVISED LASER CUT PATTERN



OPTION A



OPTION B

CONFIDENTIAL

REVISED PATTERN FOR PART HA-1A (10-13-99)

PATTERN REPEATS EVERY  $6\frac{1}{4}$  REVOLUTIONS RH THREAD

ALL DIMENSIONS IN INCHES UNLESS OTHERWISE NOTED

PART TO BE CUT FROM .106 X .134  $\phi$ , 304 STAINLESS STEEL TUBING

REVISED PATTERN TO ELIMINATE DOUBLE PASS OF LASER TO  
CUT THE HELICAL PATTERN. PARTS MUST BE STRETCHED TO THE  
DESIRED PITCH ANGLE.

READ &amp; UNDERSTOOD:

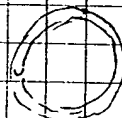
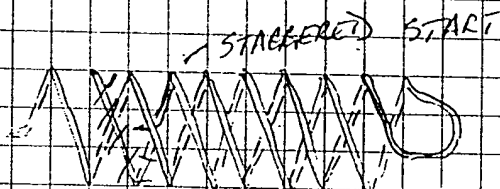
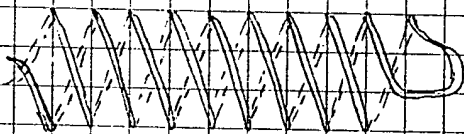
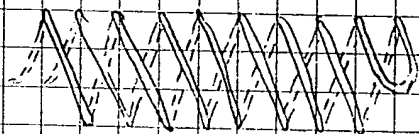
Diane M. Paten 14/30/99

Daniel J. (J) 10-1-99

88-61401

# TETHER LINE CLOSING LOOP FOR ANCHORS

THE END LOOP OF THE ANCHOR MUST BE SMOOTH, WITH NO SHARP TRANSITIONS SUCH THAT THE TETHER LINE CAN MOVE FREELY THROUGH THE CLOSING LOOP WITHOUT FRAYING, CUTTING OR ABRADING. A WELD, SOLDER JOINT, OR PINCHED COIL COULD HAVE A SHARP EDGE THAT COULD DAMAGE THE TETHER LINE WITH MOVEMENT. ONE METHOD WOULD BE TO USE A DUAL HELIX (RECOMMENDED BY CLIP LAD) WITH A CONTINUOUS PIECE OF WIRE LEAVING A SMOOTH LOOP.



STAGGERED START MAY BE USED TO HELP ASSURE PROPER ENGAGEMENT OF TETHER LINE

READ & UNDERSTOOD: Gene M. Fisher 11/3/99

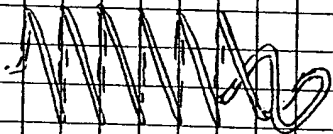
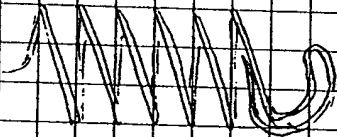
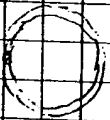
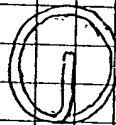
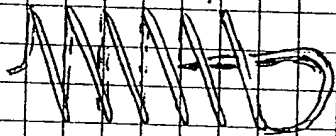
10-26-99

88-67401  
2/13

## TETHER LINE CLOSING LOOP

THE CLOSING LOOP END COULD RUN BACK  
DOWN THE MIDDLE (CENTERLINE) OF THE  
COILED ANCHOR TO ANCHOR THE END INTO END,  
OR EPI CARDIUM AND ENTRAP THE TETHER  
LINE WITHOUT ADDING FRICTION TO THE LINE

TISSUE LINE



David G. (D.G.) 10-26-99

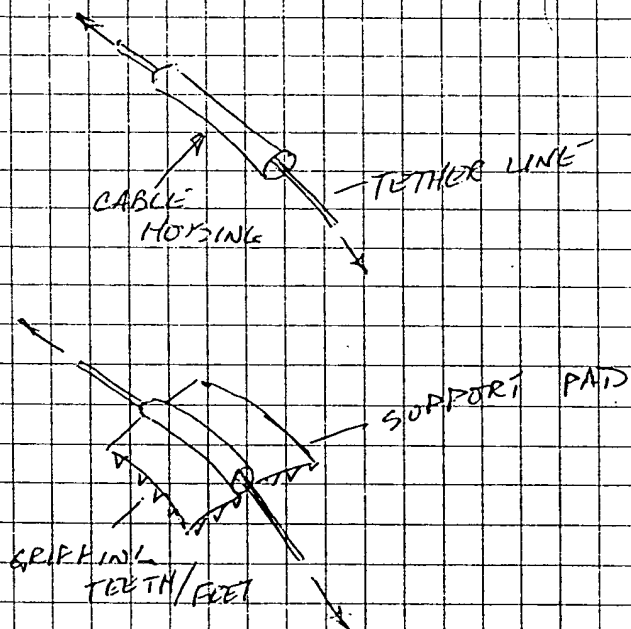
READ & UNDERSTOOD:

David Foster  
10/31/99



# TETHERLINE CABLE HOUSING/PAID

FOR THE EPICARDIAL APPLICATION OF THE TETHER LINE SYSTEM, THE TETHER LINE COULD CONCEIVABLY CUT THROUGH THE EPICARDIAL AND MYOCARDIAL TISSUE WITH TENSION AND MOVEMENT (LIKE A CABLE SAW). A CABLE HOUSING COULD REST DIRECTLY ON THE EPICARDIUM TO DISTRIBUTE THE LOAD AND ISOLATE THE TISSUE FROM AXIAL TETHERLINE MOVEMENT.



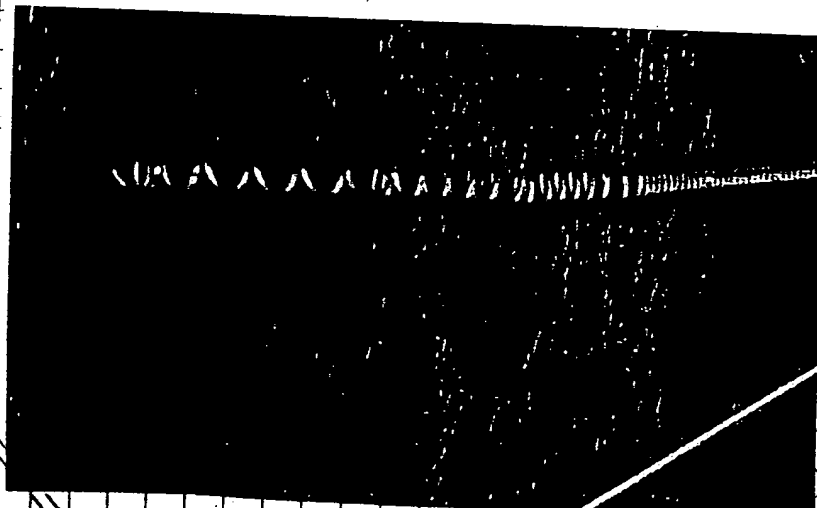
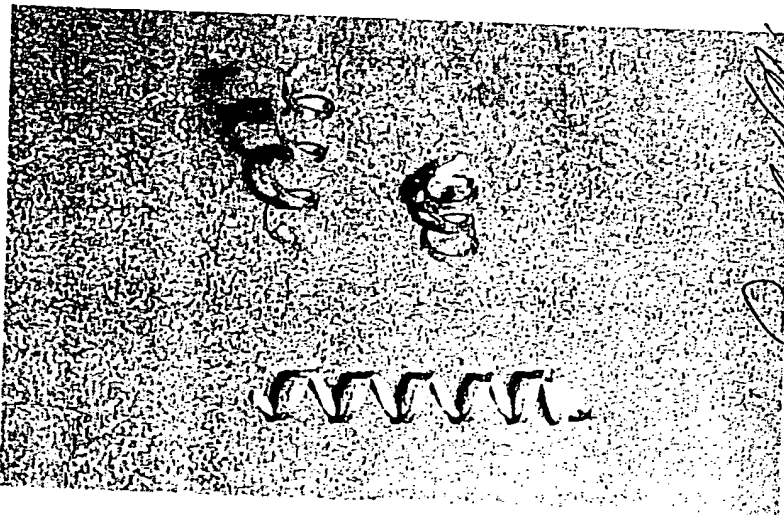
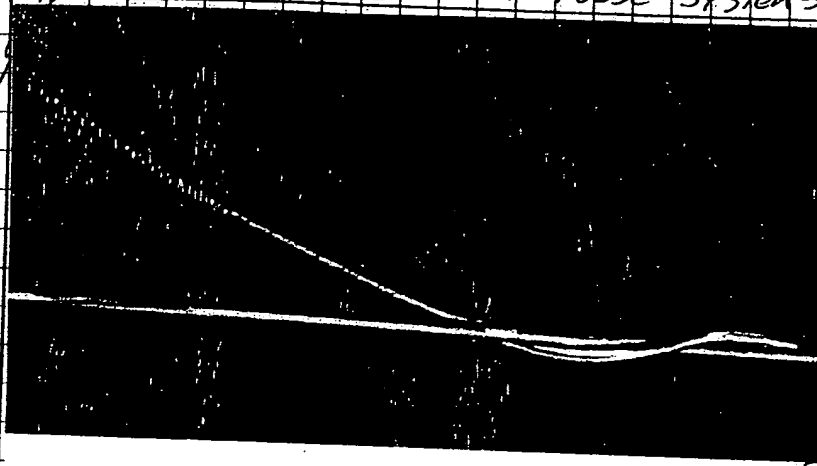
READ & UNDERSTOOD

*John M. Putter*  
10/30/99

*Paul H. G.*  
10-26-99

LASER CUT COILS FROM PULSE SYSTEMS

CUT FROM 304 STAINLESS STEEL MICROFILM



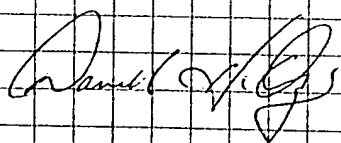
READ + UNDERSTOOD

Diane M. Carter 10/29/89

Diane M. Carter 10-29-89

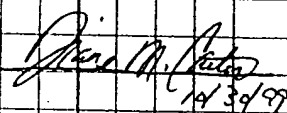
## LASER CUT COILS FROM TUBING

THE LASER CUT TUBING FROM PULSE SYSTEMS IS MUCH MORE FLEXIBLE THAN EXPECTED. THE .002" WIDE CUTS IN A HELIX ALLOWS FOR LESS LIMITED COMPRESSION AND EXPANSION OF THE INNER AND OUTER SURFACES RESPECTIVELY WHEN THE TUBING IS BENT. THE SAMPLE COILS WERE ALSO INADVERTENTLY CUT WITH A LEFT HAND HELIX RATHER THAN THE SPECIFIED RIGHT HAND HELIX. IN THE UNEXPANDED STATE, THE COILS HAVE VERY POOR TORQUE TRANSMISSION, BUT WHEN EXPANDED TO A HIGHER PITCH, TORQUE TRANSMISSION IS REASONABLE. THE SHORT ANCHOR COILS EXPAND EASILY AND MAINTAIN THEIR OUTSIDE DIMENSIONS (DIAMETER) WITH EXPANSION. THE EXPANDED ANCHOR COILS BURROW EASILY INTO SILICONE FOAM AND PORCINE MYOCARDIAL TISSUE. THERE APPEARS TO BE SUFFICIENT HOLDING FORCE IN THE FOAM AND TISSUE (COMPARABLE IF NOT EASIER THAN WIRE COIL ANCHORS).



10-29-99

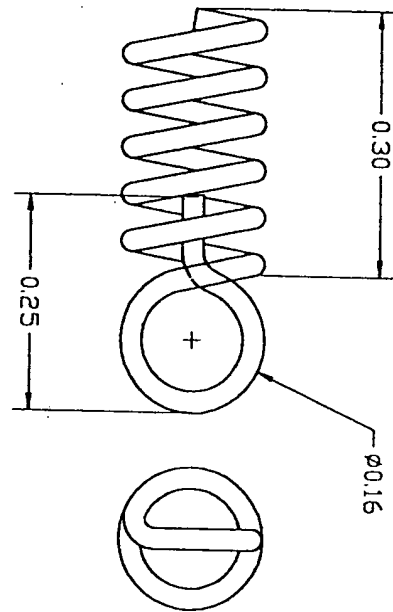
READ &amp; UNDERSTOOD

  
10/30/99

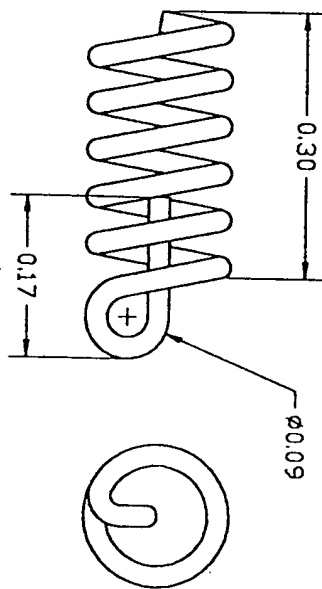
14

ANCHORS WITH TETHER LINE CLOSING LOOP

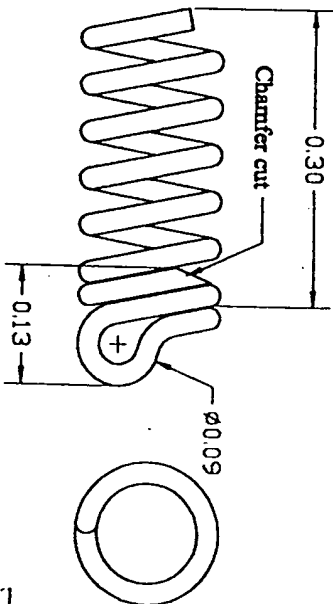
Part #  
CS-1



Part #  
CS-2



Part #  
CS-3



Confidential  
Part Numbers: CS-1, CS-2, CS-3  
10/28/99  
Paradigm Surgical  
D. Ogi (408) 396-8835

Notes:  
Material: 316 SS  
Wire diameter: 0.023"  
Spring diameter: 5/32" 0.156"  
Pitch: 20 threads per inch  
Thread Direction: Right hand thread  
Tolerances: +/- .001 ID and OD dimensions

DRAWING FAXED TO AMERICAN SPRING BY  
BILL HARRISAN 10-28-99

*[Signature]* 10-29-99

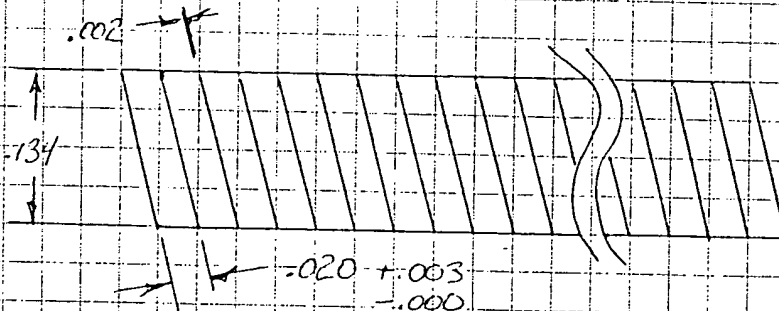
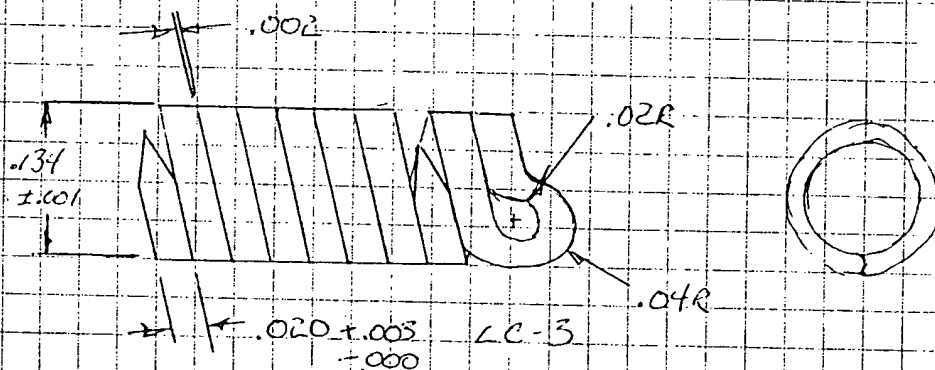
READ \*

UNDERSTOOD

*[Signature]* 10/30/99

## LASER CUT ANCHOR WITH TETHERLINE LOOP

AMERICAN SPRING HAD DIFFICULTY IN QUOTING ON PARTS CS-1, CS-2, CS-3. THE CLOSING LOOP RADIUS IS TOO TIGHT FOR .023"  $\phi$  WIRE. CS-1 WAS THE ONE THAT HAD THE MOST POTENTIAL, BUT WOULD TAKE SPECIAL TOOLING AND 4 TO 6 (SIX) WEEK LEADTIME. A MODIFIED DRAWING OF CS-3 ~~LC~~ (LC-3) WAS GIVEN TO PULSE SYSTEMS TO LASER CUT FROM A STAINLESS STEEL TUBE.

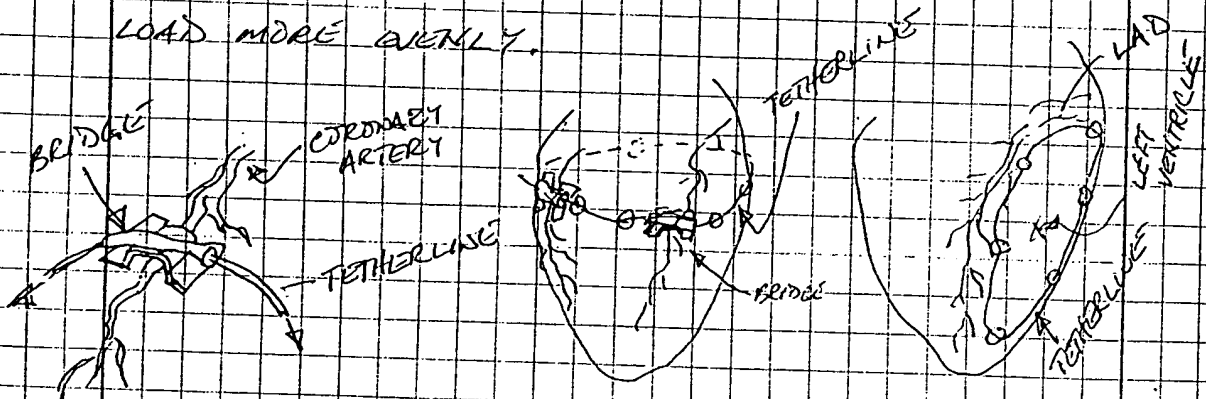


Drawn by G 11-4-99

READ + UNDERSTOOD: Mike Foster  
12/17/99

## AORTIC ASSIST / COMPLETE LOOP

ONE OF THE METHODS OF LEFT VENTRICULAR ASSIST WILL BE TO RUN THE TETHER LINE COMPLETELY AROUND THE HEART RATHER THAN JUST IN STRIPS. SECTIONS OF SIGNIFICANT CORONARY ARTERIES MAY BE BRIDGED BY AN ELEVATED TUBE SO THE CORONARY ARTERY WILL NOT BE PINCHED BY THE TETHER LINE. THE TETHERING AND ANCHORS COULD ALSO BE PLACED IN AN SPIRAL PATTERN AROUND THE EPICARDIAL SURFACE OF THE LEFT VENTRICLE. THE ADVANTAGE OF THE CONTINUOUS LOOP OF TETHER LINE WILL BE TO REDUCE THE MAXIMUM STRESS ON THE END ANCHOR TERMINATIONS AND DISTRIBUTE THE LOAD MORE EVENLY.



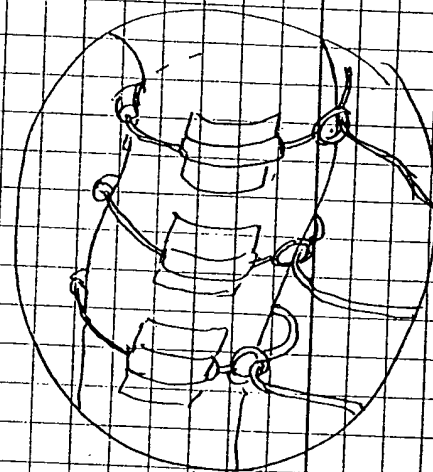
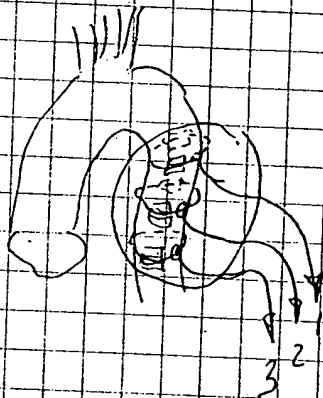
David N. G. 4-12-99

READY UNDERSTOOD

Pharm/Int 12/18/99

## AORTIC ASSIST

THE CONTINUOUS LOOP TETHERLINE COULD ALSO BE USED AS AN AORTIC ASSIST DEVICE TO RELIEVE LEFT VENTRICULAR WORKLOAD BY SEQUENTIALLY CONTRACTING THE AORTIC WALL TO HELP PUMP BLOOD THROUGH THE AORTA. THE CONTRACTIONS COULD BE TIMED WITH THE CONTRACTIONS OF THE LEFT VENTRICLE TO ENHANCE FLOW RATE.



THE SEQUENTIAL "SQUEEZE" WILL HELP ADVANCE BLOOD MUCH LIKE A PERISTALTIC PUMP. PADS COULD BE USED TO DISTRIBUTE THE CONTRACTING LOAD OF THE TETHERLINES.

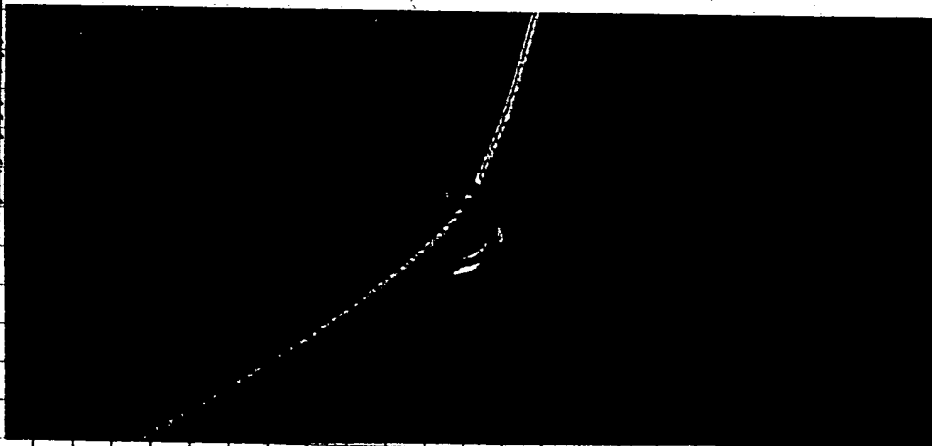
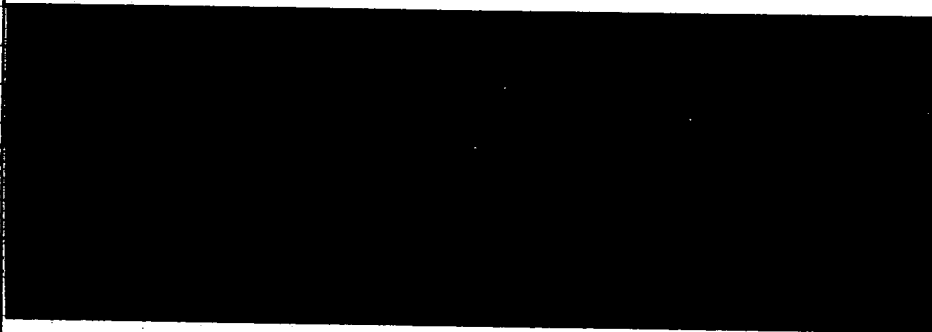
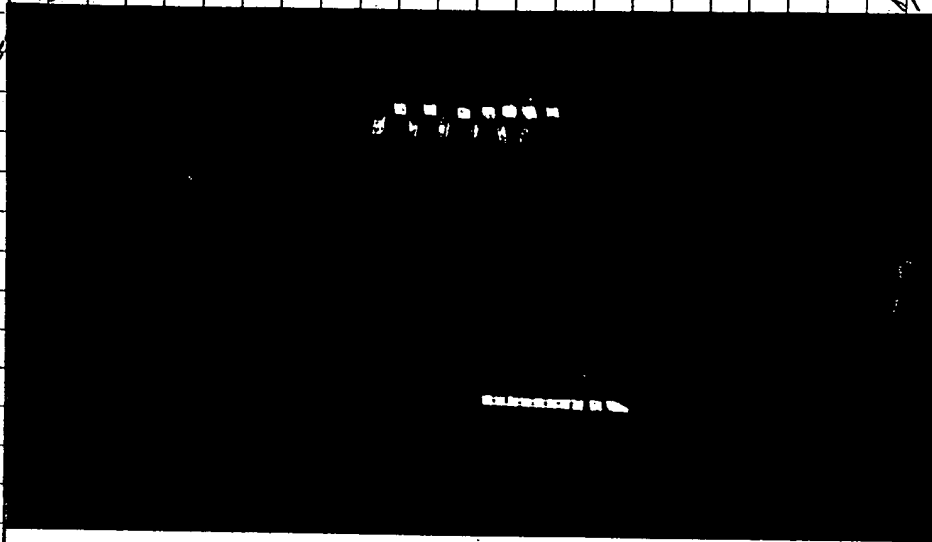
David G. G.

11-12-99

READ &  
UNDERSTOOD

David G. G. 12/17/99

LASER CUT ANCHOR WITH TETHER LINE LOOP



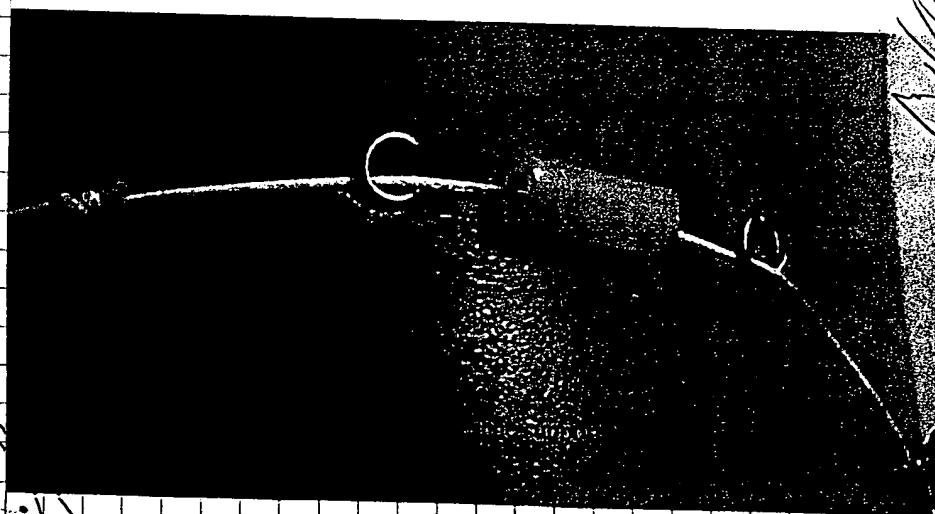
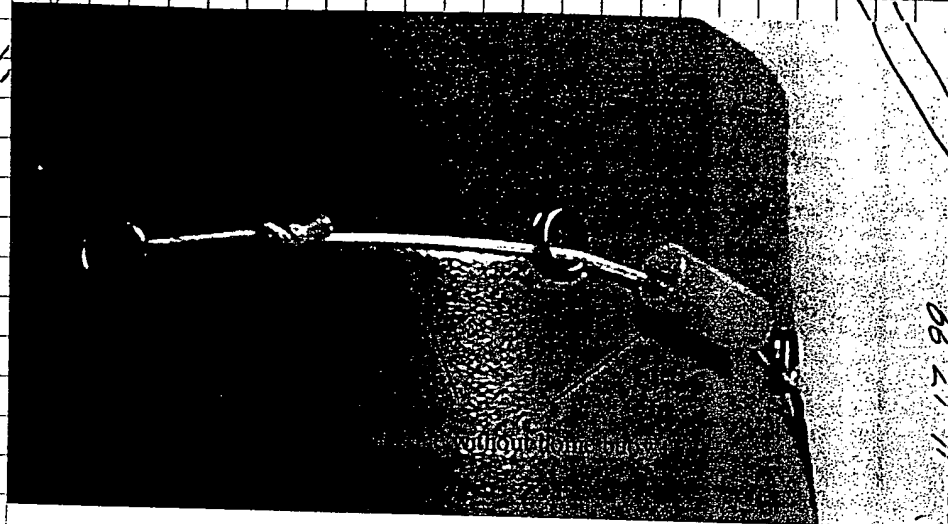
Shane 11-17-99

READ &  
UNDERSTOOD

Shane 12/19/99



## HOME BOOT STRAIN RELIEF



HOME BOOT DISTRIBUTES THE POINT LOADING  
OF THE TETHERLINE TO REDUCE STRESS ON EPICARDIUM.

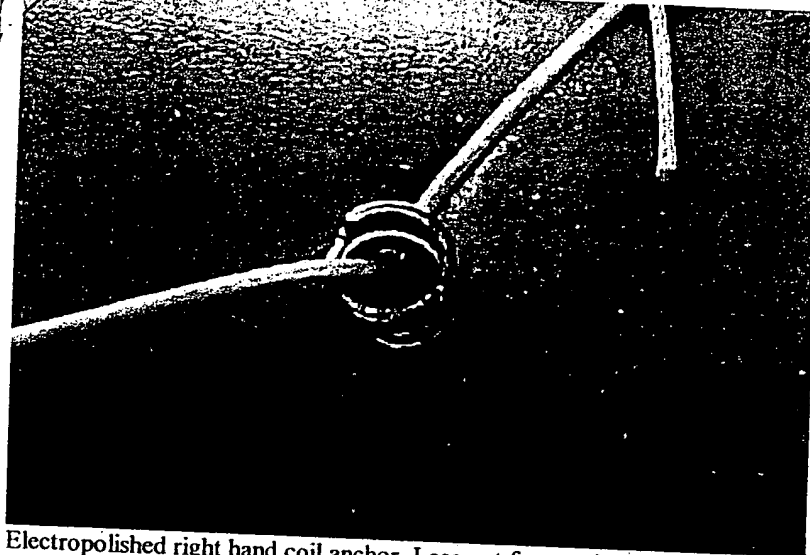
David V. G. 11-17-99

READ

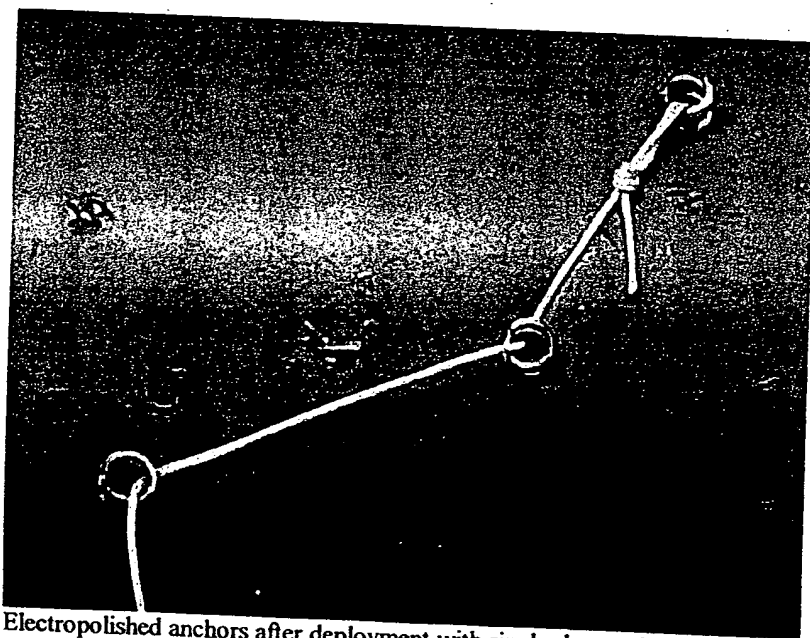
UNDERSTOOD

John F. 12/18/99

## ELECTRO POLISH THE RHT LASERCUT ANCHORS



Electropolished right hand coil anchor. Lasercut from stainless steel tubing, then electropolished.



Electropolished anchors after deployment with single shot tool with right hand thread block. Polished parts allow easier movement of tetherline.

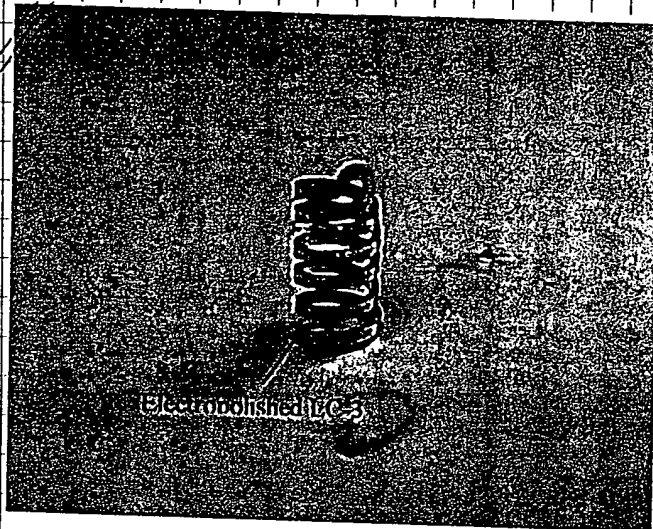
James H. G. 11-18-99

ROAD,  
JUN 2000-2003

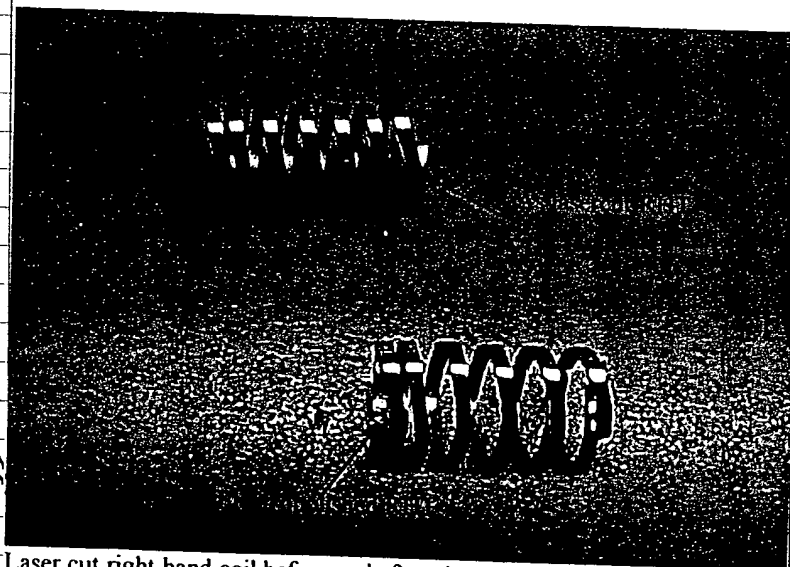
Steve Carter 2/9/99

5th Apr. 11:00 AM '99

ELECTROPOLISHED LC-3 ANCHOR



Electropolished at Pullbrite, allows tetherline to slide more freely.



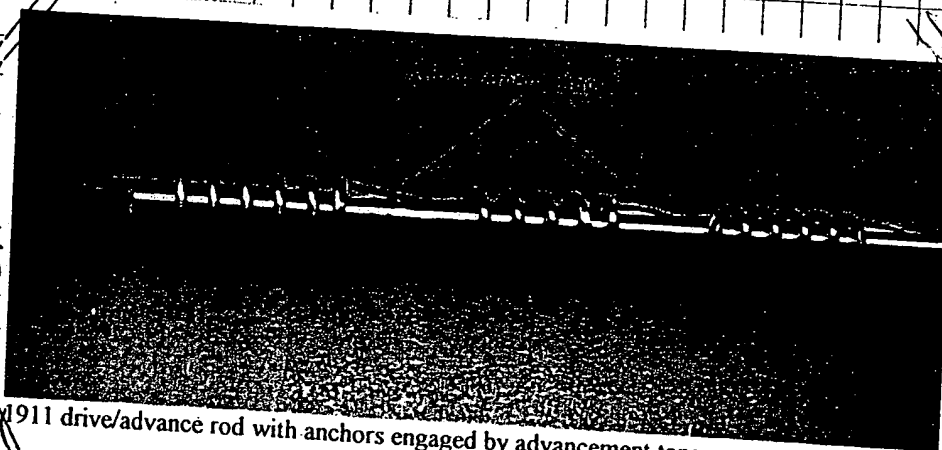
Laser cut right hand coil before and after electropolishing.

*David W. G.* 11-18-99

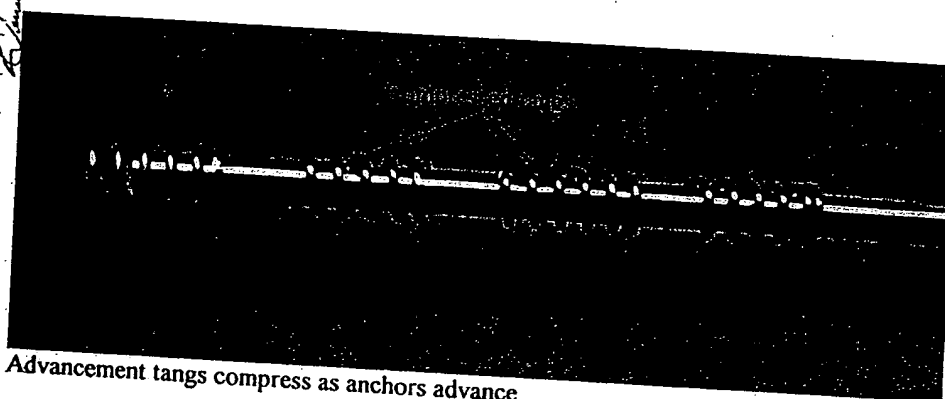
READY  
UNDERSTOOD

*Steve Carter* 12/9/99

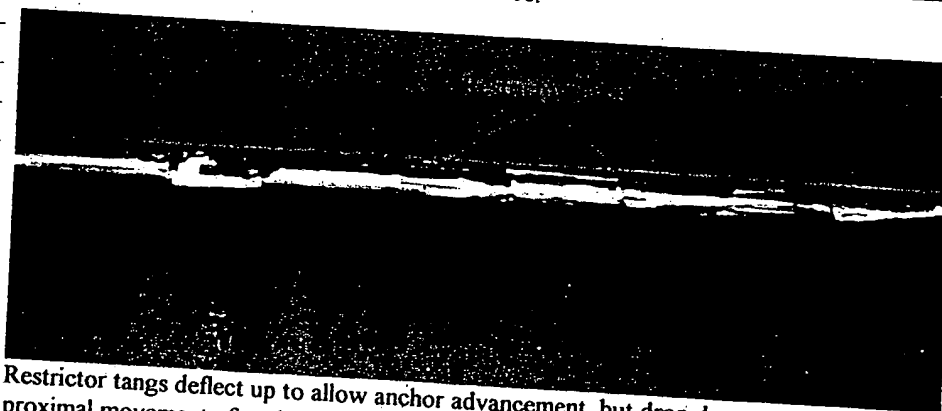
# 1911 ANCHOR ADVANCEMENT SYSTEM (SEE LNB #3 PP 4,5)



1911 drive/advance rod with anchors engaged by advancement tangs.



Advancement tangs compress as anchors advance.



Restrictor tangs deflect up to allow anchor advancement, but drop down to restrict proximal movement of anchors. Tangs reduced from .015" to .007" for more flexibility.

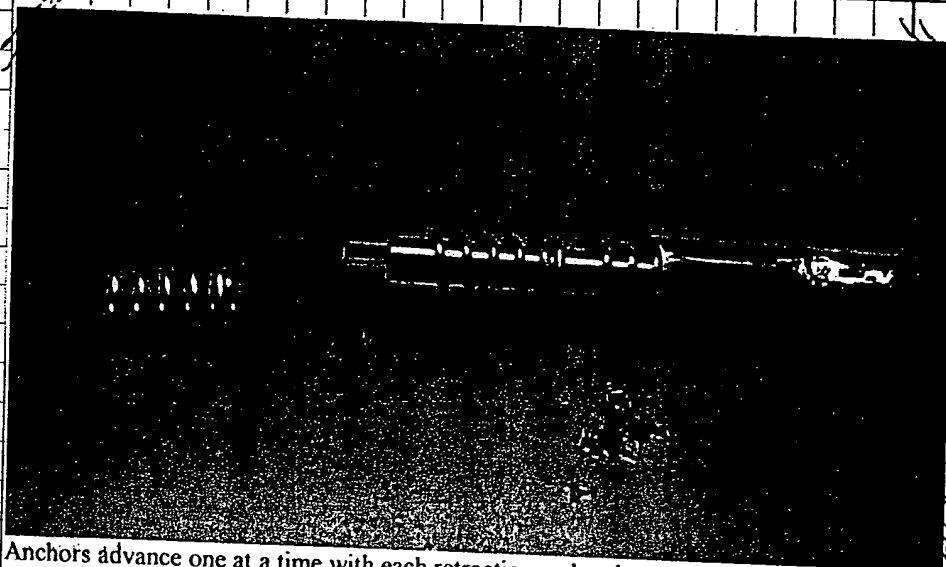
CONCEPT AND DRAWING CAPTURED IN BILL HARTIGAN'S  
NOTEBOOK.

James H. G. 11-18-99

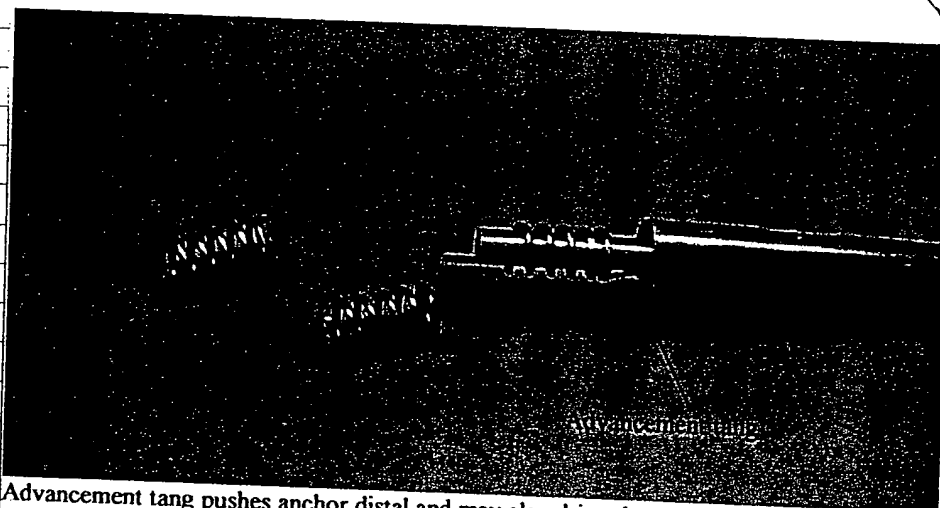
READ  
& UNDERSTOOD

Diane (July 10/11/99)

1911 CONTINUED



Anchors advance one at a time with each retraction and advancement of the drive/advancement shaft.



Advancement tang pushes anchor distal and may also drive the anchors helically.

RESTRICTOR TANGS ARE BENT INWARD .010-.020" TO RESTRICT PROXIMAL MOVEMENT OF ANCHORS. ADVANCEMENT TANGS ARE BENT OUTWARD .010-.030" TO ADVANCE ANCHORS DISTALLY, BUT RETRACT TO ALLOW RETRACTION OF DRIVE ROD TO INDEX THE NEXT ANCHOR.

Donnell G.

11-18-99

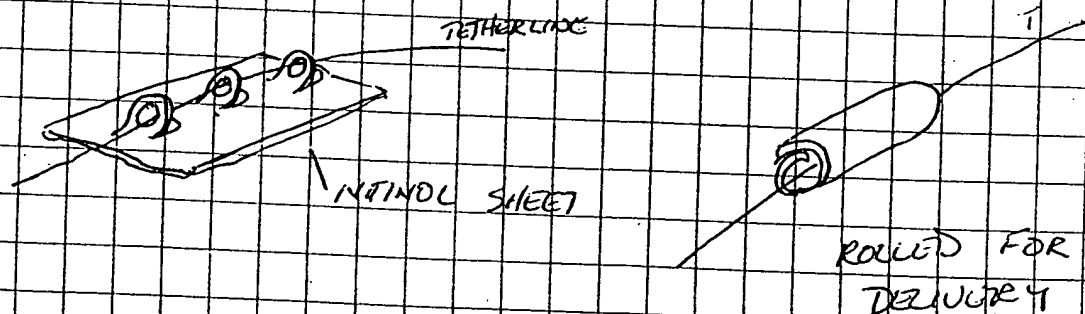
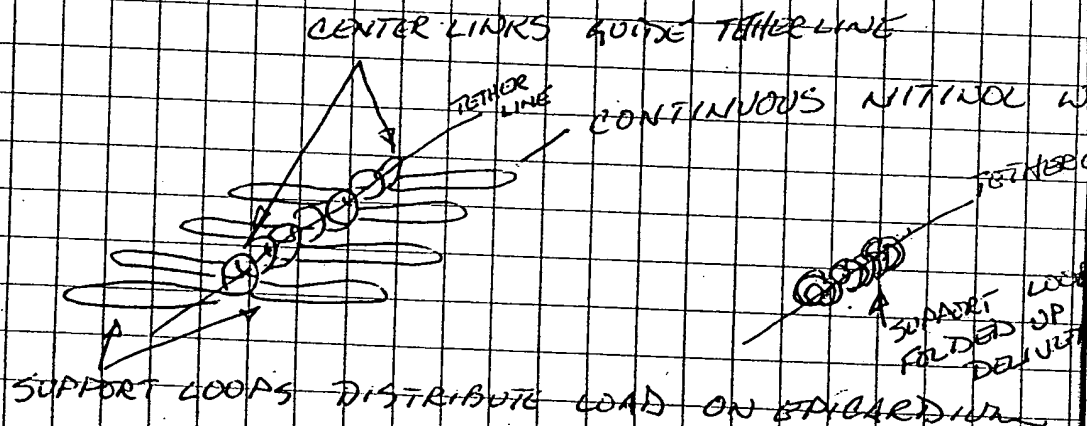
ROAD

UNDERSIDES

Steve Smith, 12/10/99

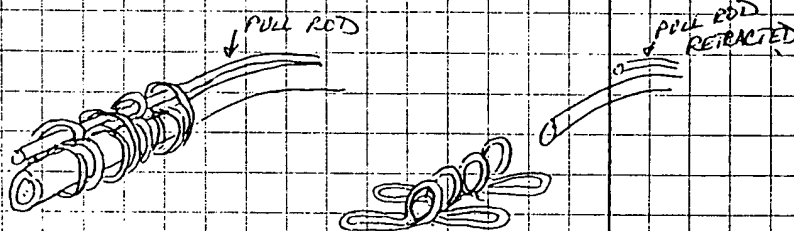
## TETHERLINE SUPPORT / STANDOFF

PER PAGE 11 OF THIS NOTEBOOK, A SUPPORT PAD MAY BE NECESSARY TO DISTRIBUTE THE LOAD TO THE EPICARDIUM FROM THE TETHERLINE WHEN TENSIONED. A NITINOL WIRE, OR SHEET CAN BE FORMED INTO A SUPPORT PAD WITH TETHERLINE GUIDES.



## TETHERLING SUPPORT PAD DELIVERY

THE NITINOL WIRE SUPPORT PAD / STANDOFF CAN BE ROLLED UP AROUND THE CENTRAL TETHERLING AXIS TO REDUCE THE DELIVERY PROFILE. THIS REDUCED PROFILE CAN THEN BE LOADED INTO A DELIVERY TUBE, CAPTURE DEVICE / SLEEVE, OR HZD COMPRESS WITH A PULL PIN / LINE. THE COMPRESSED STANDOFF CAN BE DELIVERED OVER THE TETHERLING, BETWEEN THE ANCHORS. RADIOPAQUE MARKERS CAN BE ADDED TO THE SUPPORT PADS FOR VISUALIZATION AND TO AID ORIENTATION. A FOLDED WIRE SUPPORT PAD COULD BE MOUNTED ON A TORQUABLE CATHETER SHAFT WITH A RETRACTABLE PIN TO KEEP ORIENTATION AND DEPLOY THE SUPPORT PAD ON THE EPICARDIAL SURFACE.



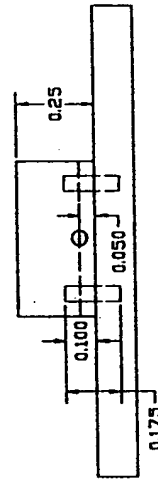
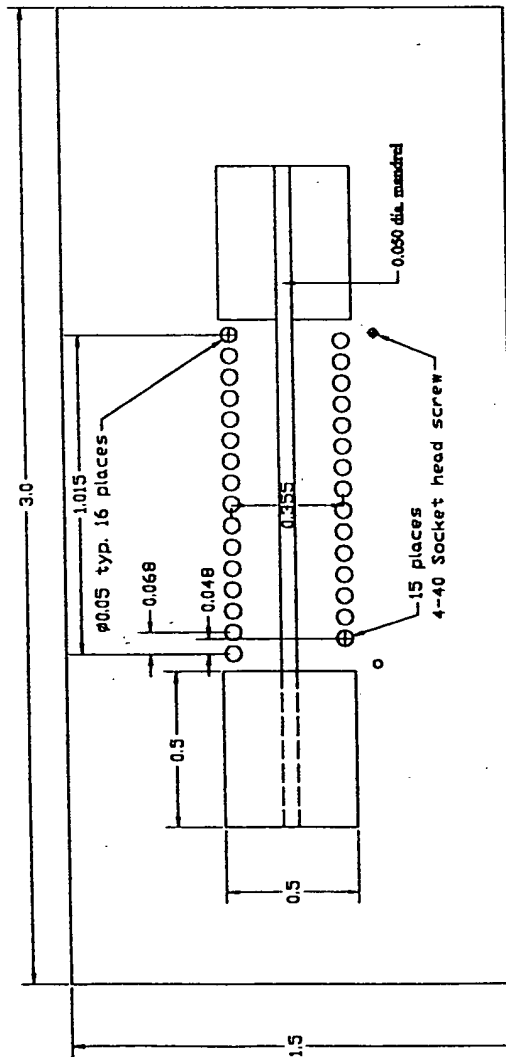
David H. G. 11-29-99

READ  
UNDERSTOOD

David H. G. 12/19/99

# TETHERLINE SUPPORT AND CURING FIXTURE

*Don H. G.* 12-2-99



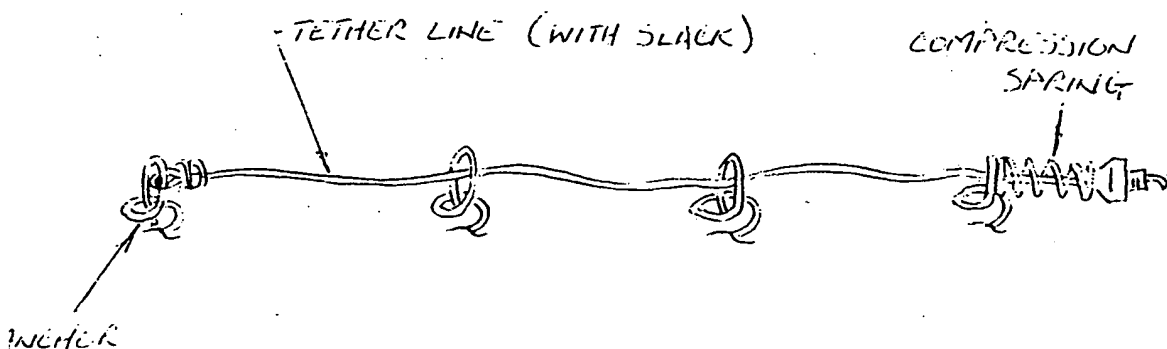
*Don H. G.* 12-2-99

READ + UNDERSTAND

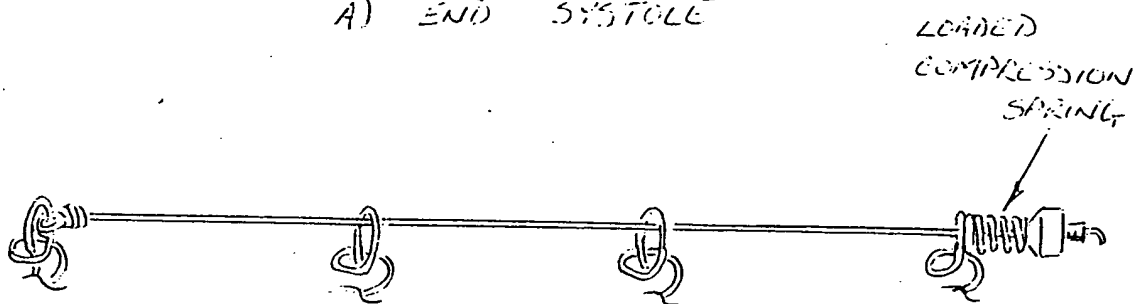
*Pine Carter* 12/1/99



## TETHER LINE WITH COMPRESSION SPRING IN SERIES



A) END SYSTOLE



B) END DIASTOLE

FIGURE 3

TETHER LINE WITH COMPRESSION SPRING IN SERIES

R. A. G.

12-2-97

R. A. G.

11-30-97

READ

UNDERSTOOD

David L. G. 12/19/97

## ACTIVE LEFT VENTRICULAR ASSIST CATHETER

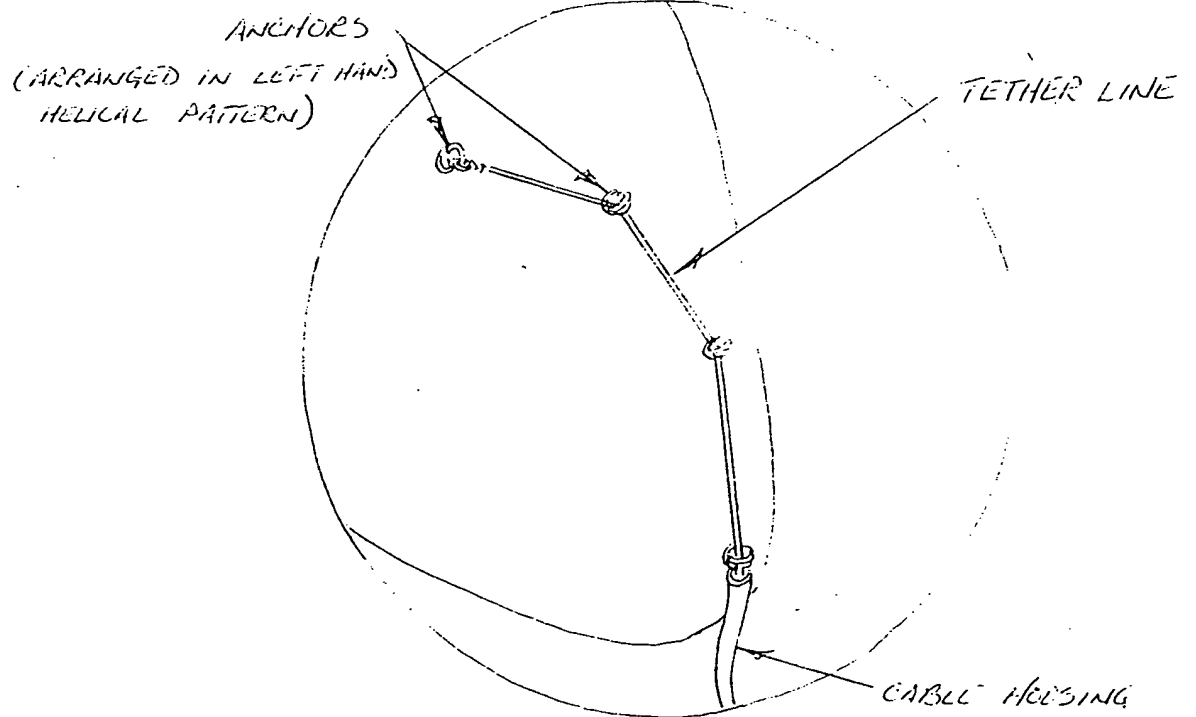
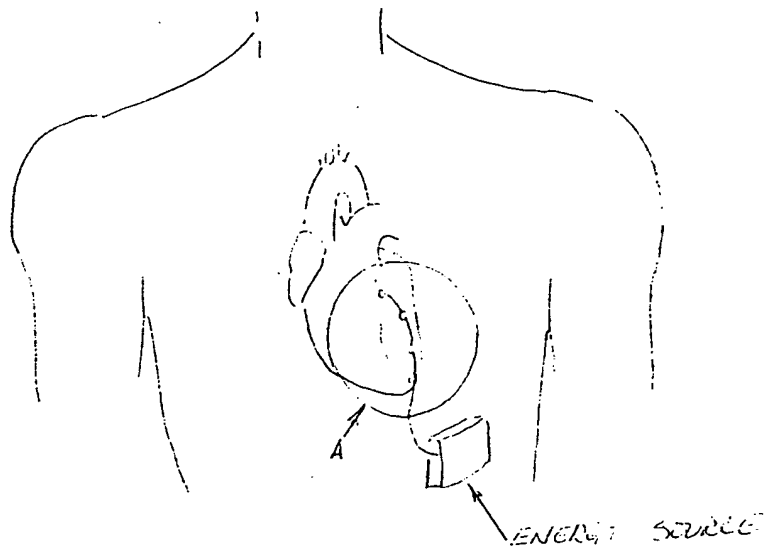


FIGURE 10

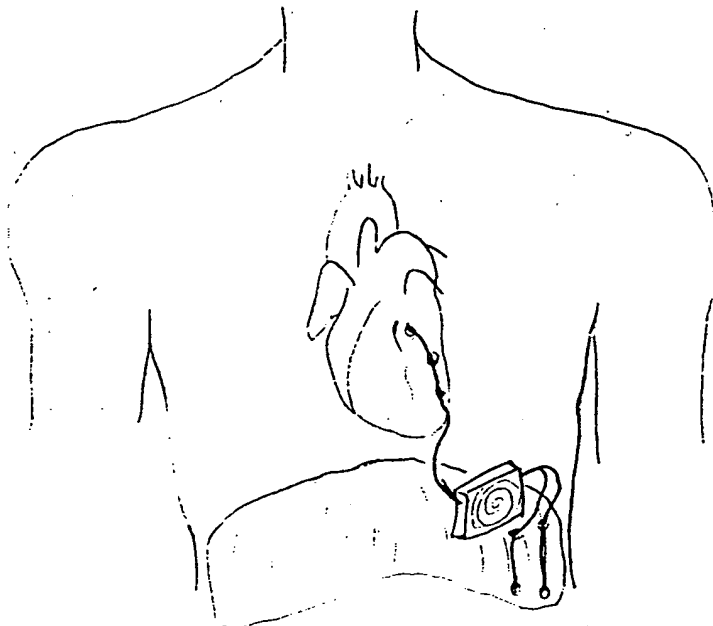
DETAIL A

David J. (P) 12/1/99

READY + UNDERSTOOD

None (date) 12/1/99

DIAPHRAGM DRIVEN LEFT VENTRICULAR ASSIST.



FIGURES 11 + 12

INPUT FROM DIAPHRAGM TO SPRING MECHANISM, THEN  
OUTPUT TO CARDIAC HARNESS.

Randall H. G. 12/2/99

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UNDERSTOOD

Dave Carter 12/19/99

## CHARACTERIZE ANCHOR MOVEMENT FOR GATING

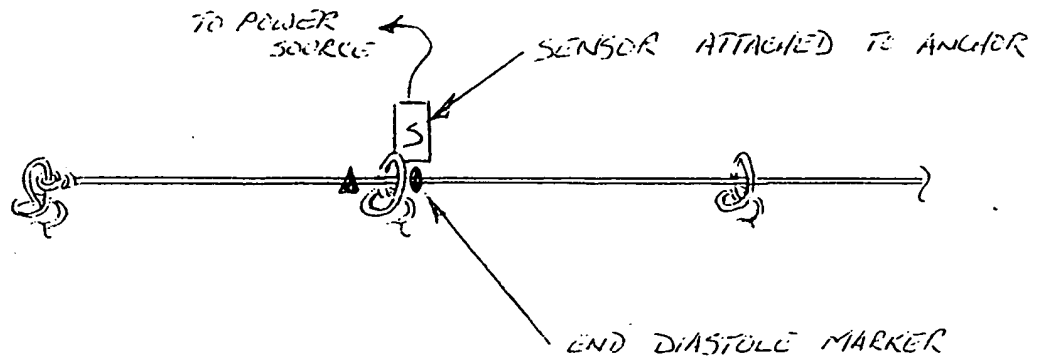


FIGURE 13

GATING / CHARACTERIZING ANCHOR MOVEMENT AT END DIASTOLE.

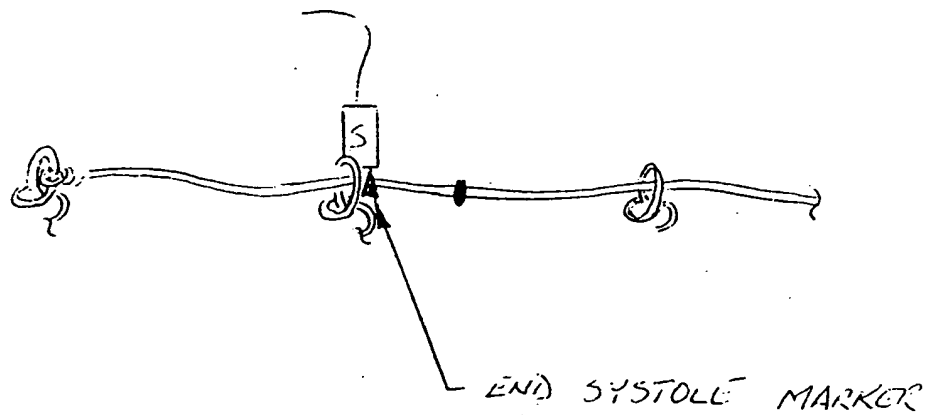


FIGURE 14

GATING / CHARACTERIZING ANCHOR MOVEMENT DURING SYSTOLE.

David H. G. 12/2/99

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UNDERSTOOD

David H. G. 12/19/99

## ANCHORS WITH PULLEYS

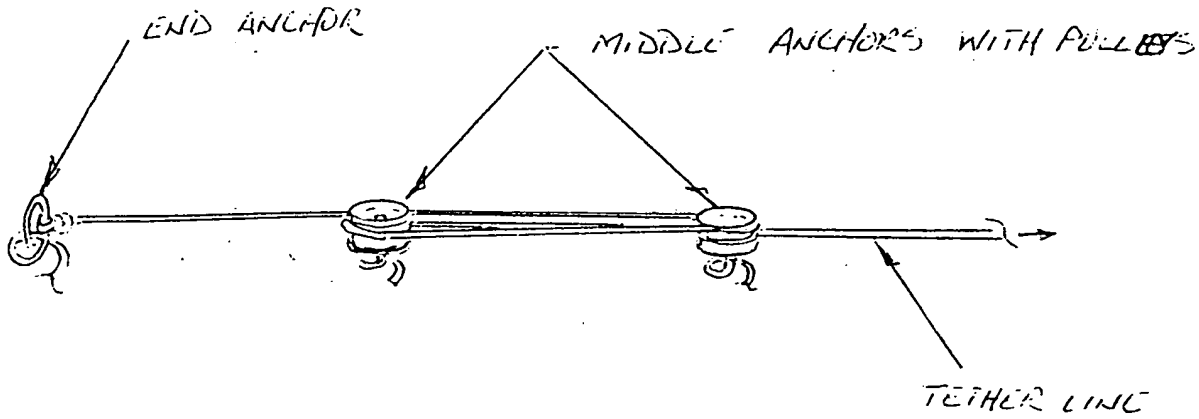


FIGURE 19

ANCHORS WITH PULLEYS ALLOW BACK LOOPING,  
TO DISTRIBUTE LOADING AND "MECHANICAL  
ADVANTAGE".

Don H. G. 12/2/95

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Done (Antis) 12/19/97

## ANCHORS USED FOR PAGING OR SENSING

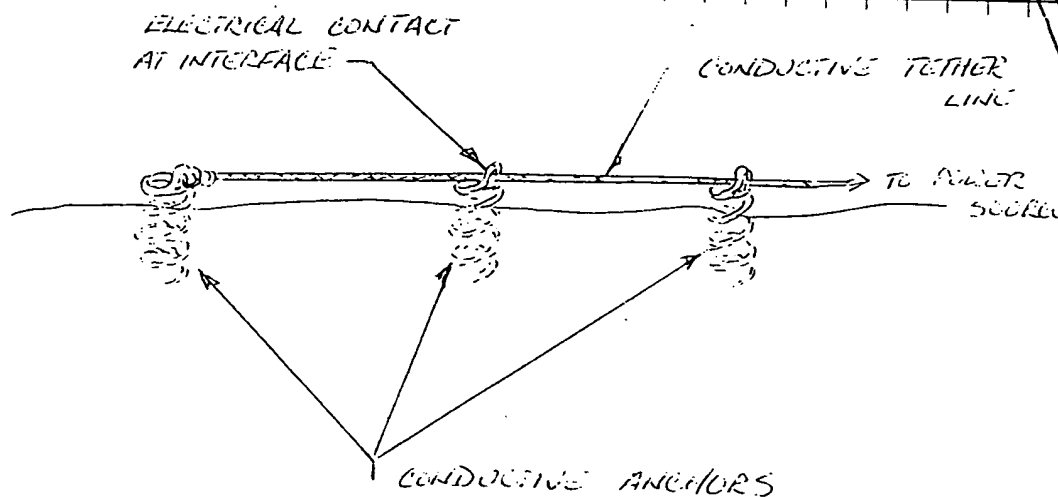


FIGURE 23

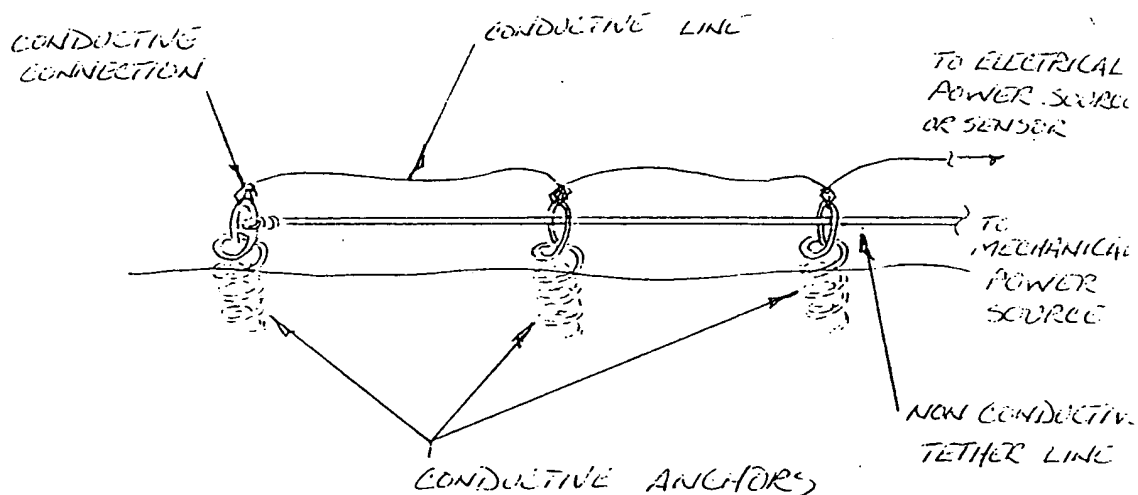


FIGURE 24

*Read H. G.* 12/2/99

Read  
understood

*Steve Carter*  
12/19/99

TETHER LINE SUPPORT PAD / BRIDGE

CONFIDENTIAL

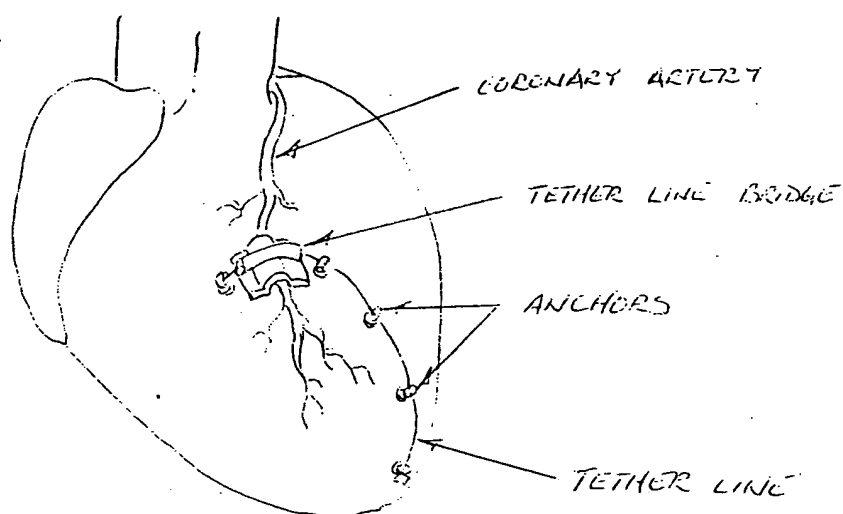


FIGURE 25

TETHER LINE CORONARY ARTERY BRIDGE.

D. H. G.!

12/2/99

READ

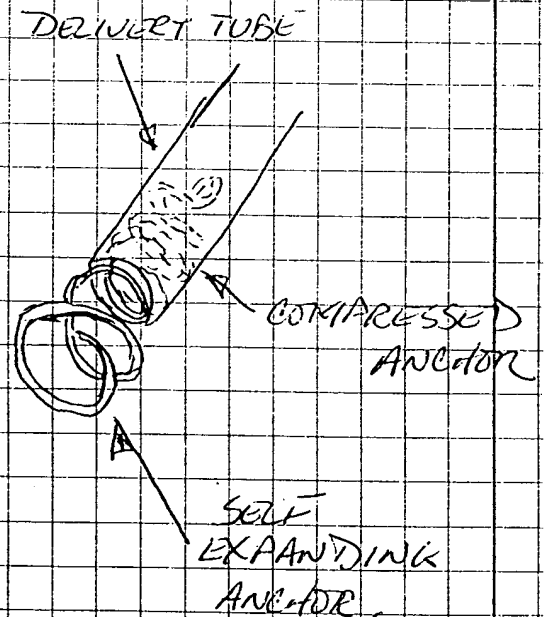
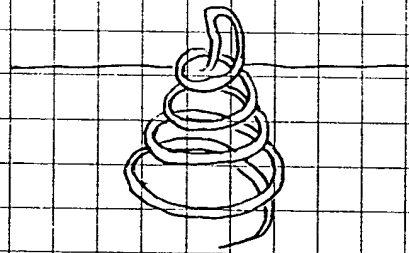
UNDERSTOOD

D. H. G.

12/19/99

## CONICAL COIL ANCHOR

TO IMPROVE THE LATERAL LOAD CAPABILITY OF THE ANCHOR, THE PART CAN HAVE A CONICAL, OR PYRAMID SHAPE TO CARRY GREATER LOAD DEEPER INTO THE MYOCARDIUM. THE COIL COULD BE MADE FROM NITINOL WIRE TO GIVE IT SHAPE MEMORY TO BE DELIVERED FROM A STRAIGHT, CYLINDRICAL TUBE, BUT WOULD EXPAND OUTWARD AS IT BURROWS INTO TISSUE.



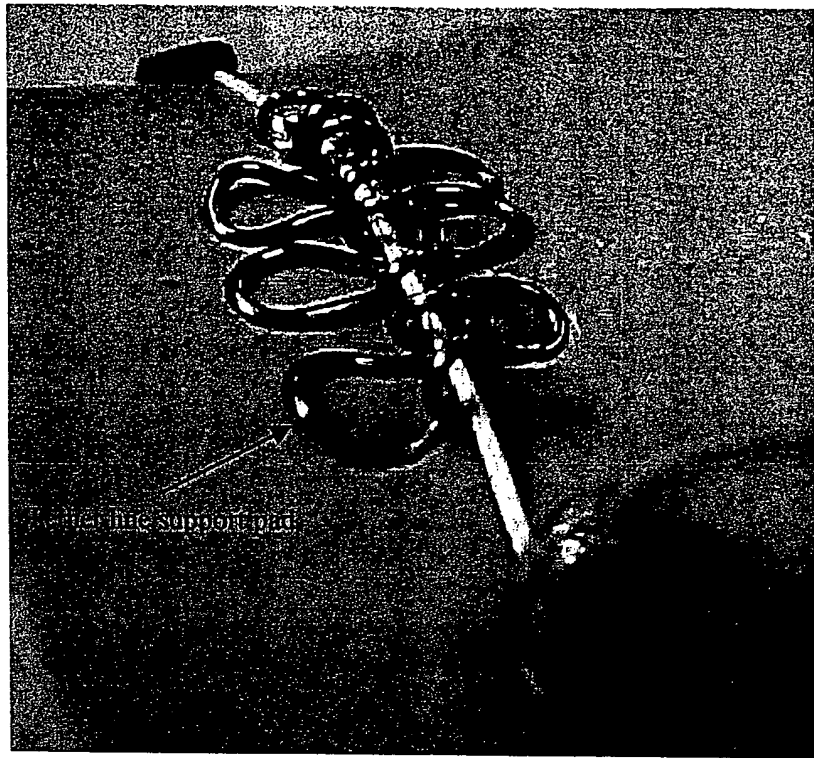
David H. G. 12/7/99

READ  
T. M. M. M. M.

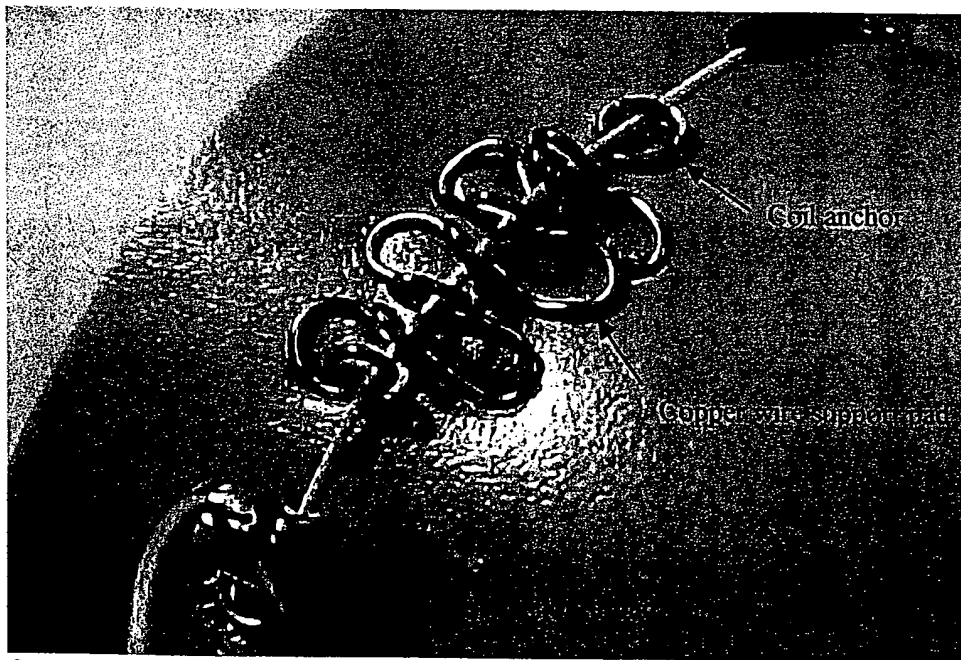
David H. G. 12/19/99



## TETHER LINE SUPPORT PAD/STANDOFF



Note, support pad distributes the load from the tether line for reduced trauma to tissue.



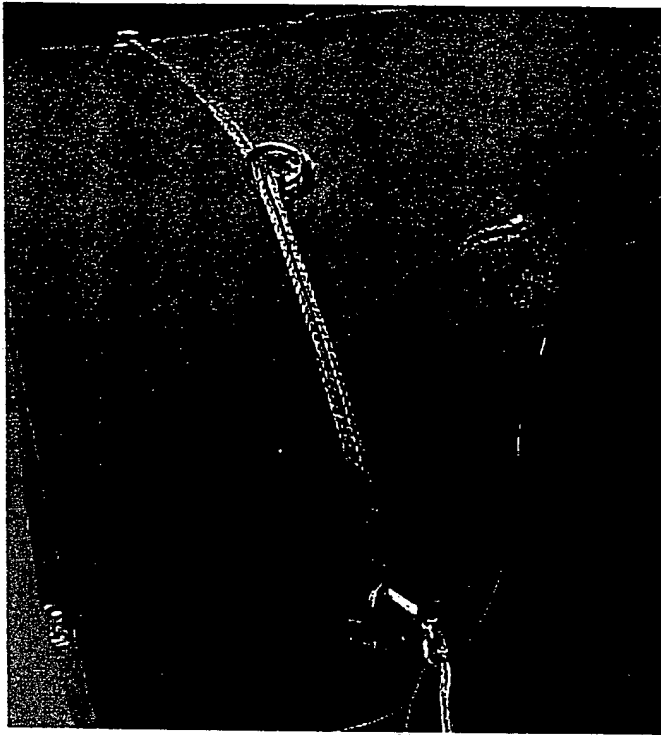
Copper wire mock-up distributes tether line load. Nitinol support pads will allow folding to a smaller profile for thorascopic delivery.

David H. G. 12-8-99

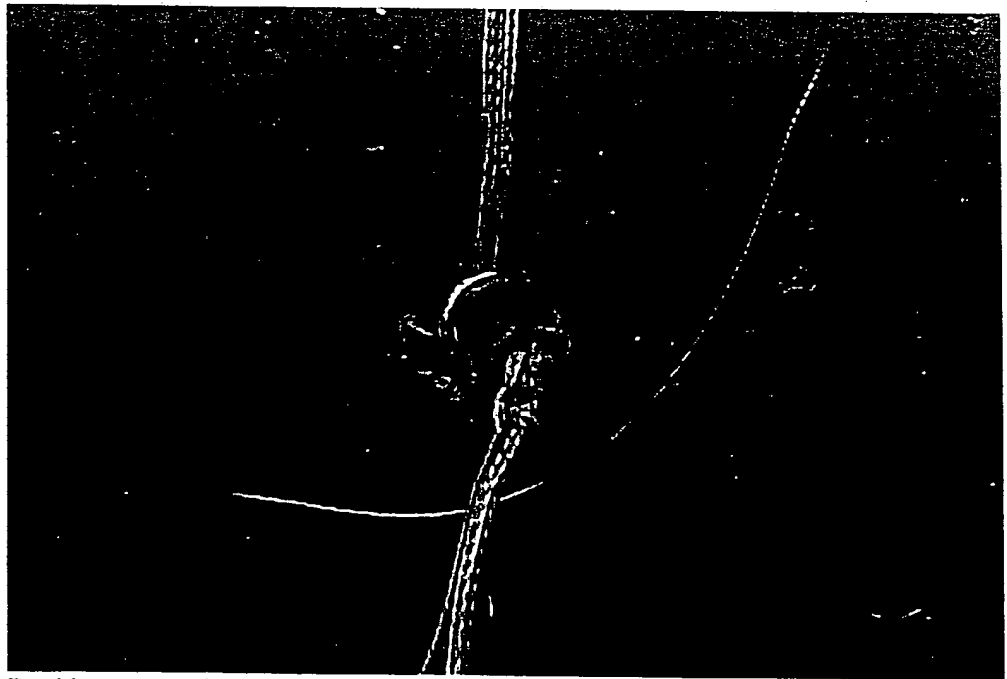
RECID (UNDERSTOOD)

David H. G.  
12/19/99

DUAL LUMEN TERMINATION BOTTOM (PS-1)



Done 12/8/99



Dual lumen termination plug.

Done 12/8/99

READY FOR INSPECTION

Done Carter 12/19/99

## TETHER LINE STAND-OFF

Tether line stand-off.

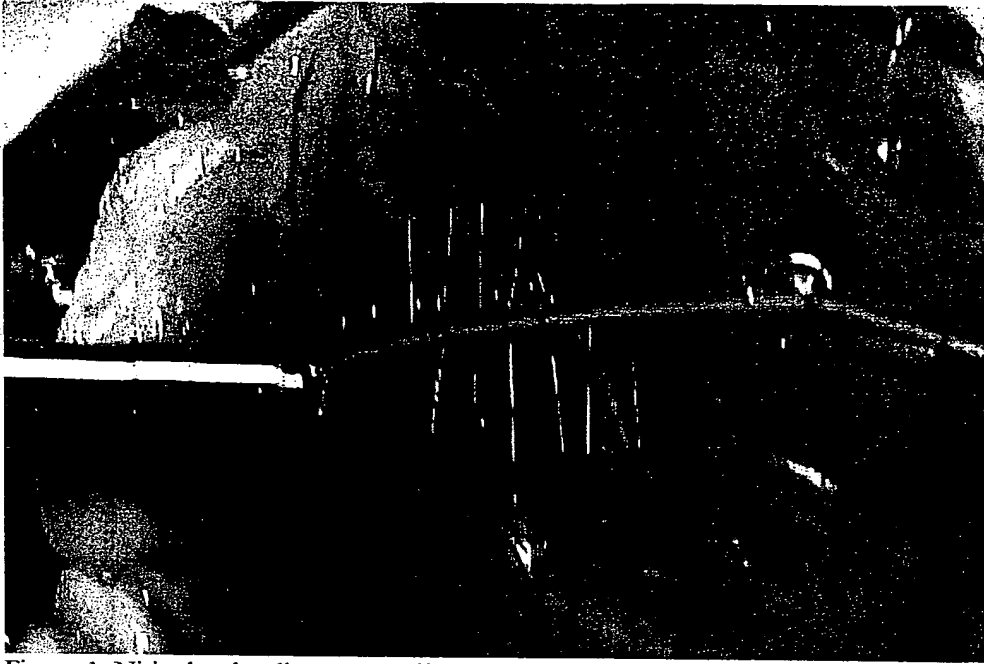
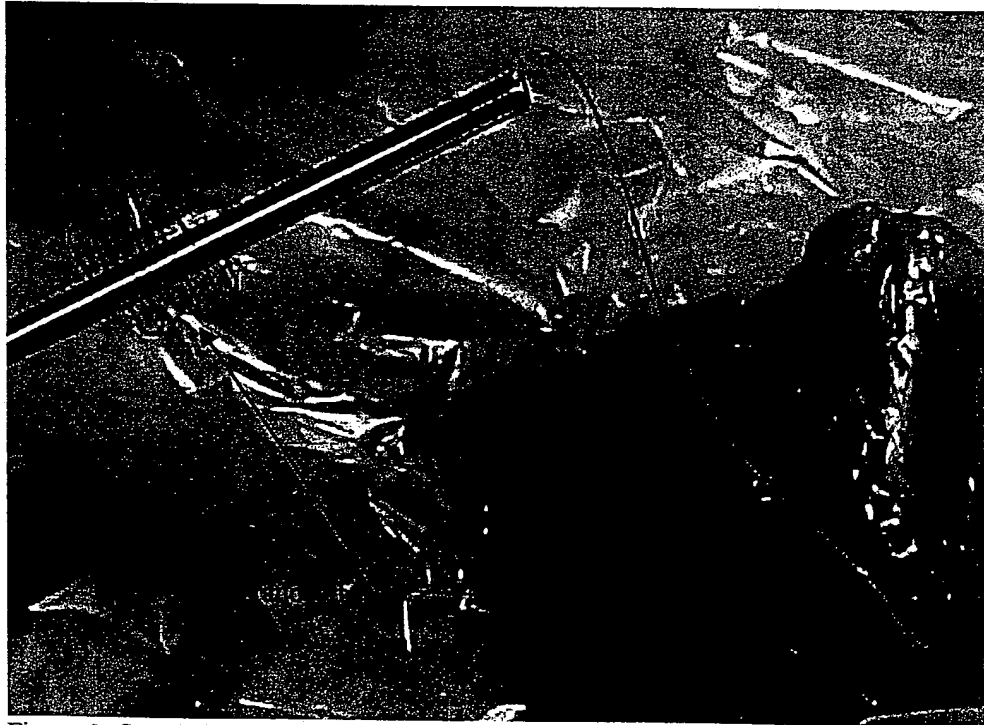


Figure 1: Nitinol tether line stand-off distributes epicardial load from the tether line.



• Figure 2: Standoff can be delivered over the shaft of the anchor delivery system. The nitinol stand-off can be folded down around the delivery shaft and captured by a sleeve for smaller delivery profile.

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*David H. G. S.* 12/13/99

READ & UNDERSTOOD

*David H. G. S.*  
12/19/99

TETHER LINE STAND-OFF CONTINUED



Figure 3: Tether line stand-off is delivered over the tether line, capturing the line through the center coil.

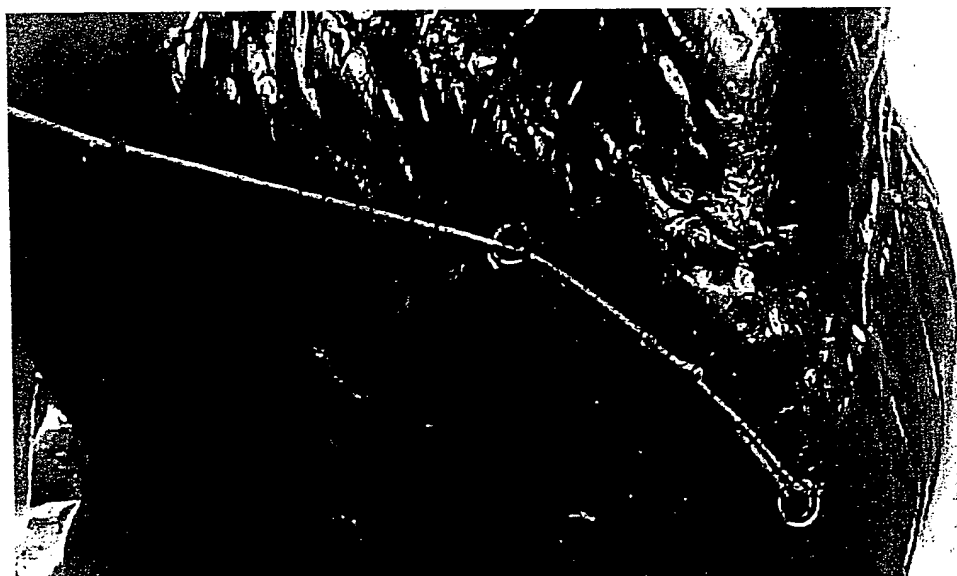


Figure 4: Stand-offs may be trimmed to varying lengths and spaced between anchors.

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*Ronald H. [Signature]* 12/13/99

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\* UNDERSTOOD

*Marie Carter* 12/17/99

TETHER LINE STAND-OFF, (CONTINUED)

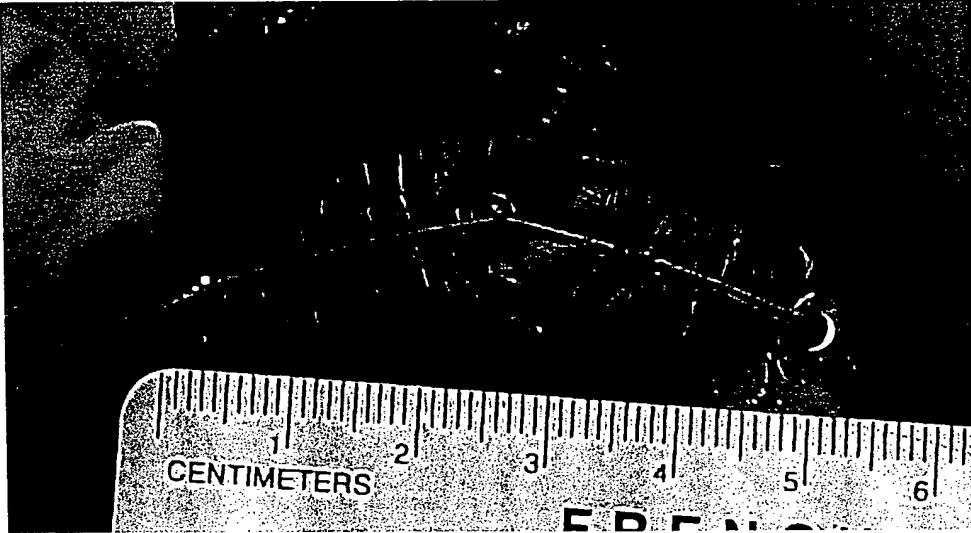


Figure 5: Stand-offs distribute the load from the tether line.



Figure 6: Stand-off allows tether line to freely slide, without cutting into the tissue. Legs of the stand-off follow the contour of the tissue and accommodate surface changes during the cardiac cycle.

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*Walter H. H. 12/13/99*

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✓  
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*Shane Carter 12/19/99*

## CARDIAC HARNESS PATTERNS



Figure 1: Anchors and tether line can be arranged in a left hand helical pattern from the apex of the left ventricle to the ventricular septum.

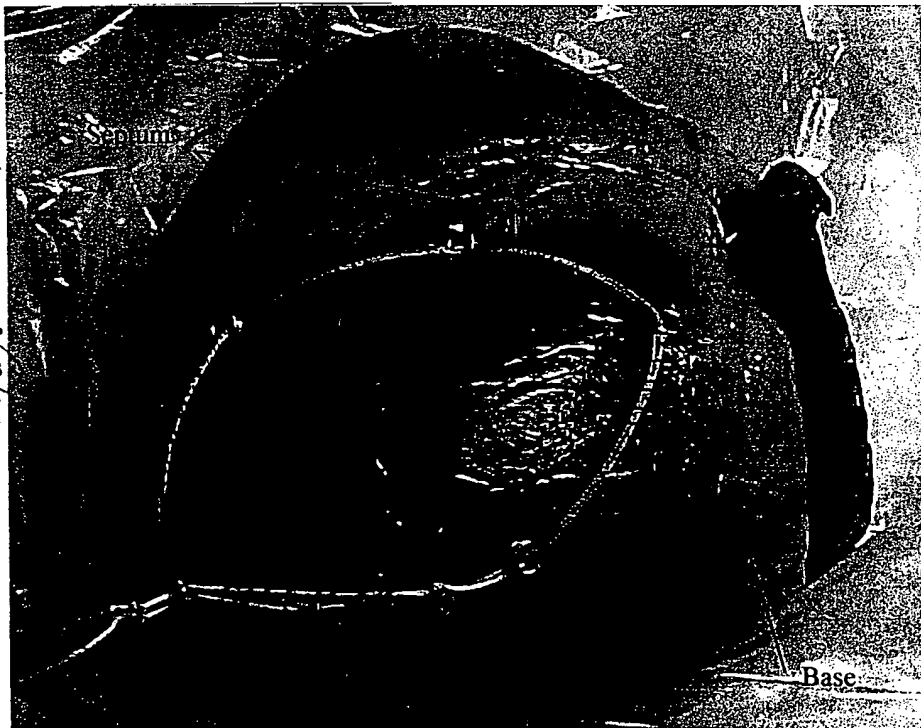


Figure 3: The harness can also be arranged in a continuous loop, to more evenly distribute the load to each anchor from the tensioned tether line. The harness may be a passive left ventricular assist device, or may be powered, to be an active assist device.

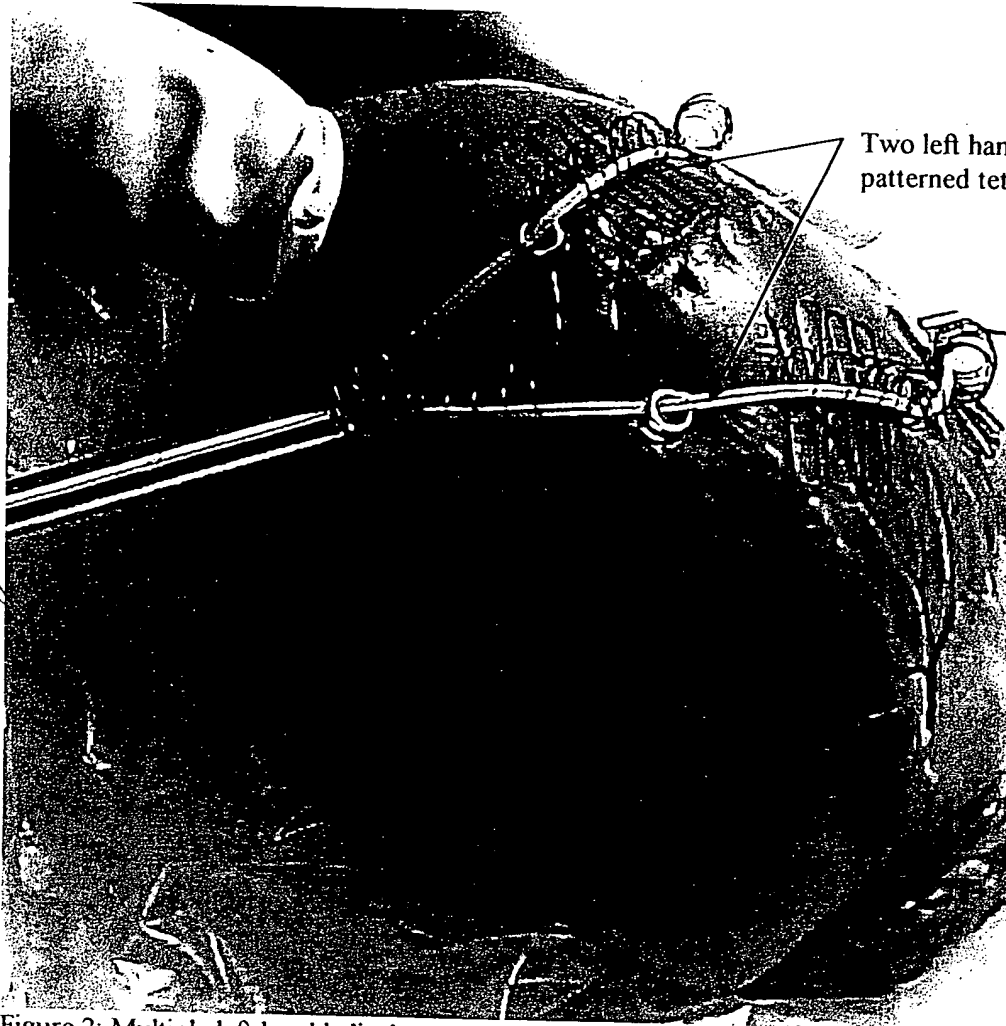
David H. 12/13/99

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Neal

12/19/99

## CARDIAC HARNESS PATTERNS CONTINUED



Two left hand helical  
patterned tether lines

Figure 2: Multiple left hand helical patterns may be arranged on the left ventricle. As shown above, they may share a common end anchor and terminate as a passive harness, or be driven as an active ventricular assist.

David H. G. 12/13/99

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Mark Carter 12/19/99

## CARDIAC HARNESS PATTERNS



Figure 4: The pattern may start at the apex of the left ventricle and move toward the base of the heart

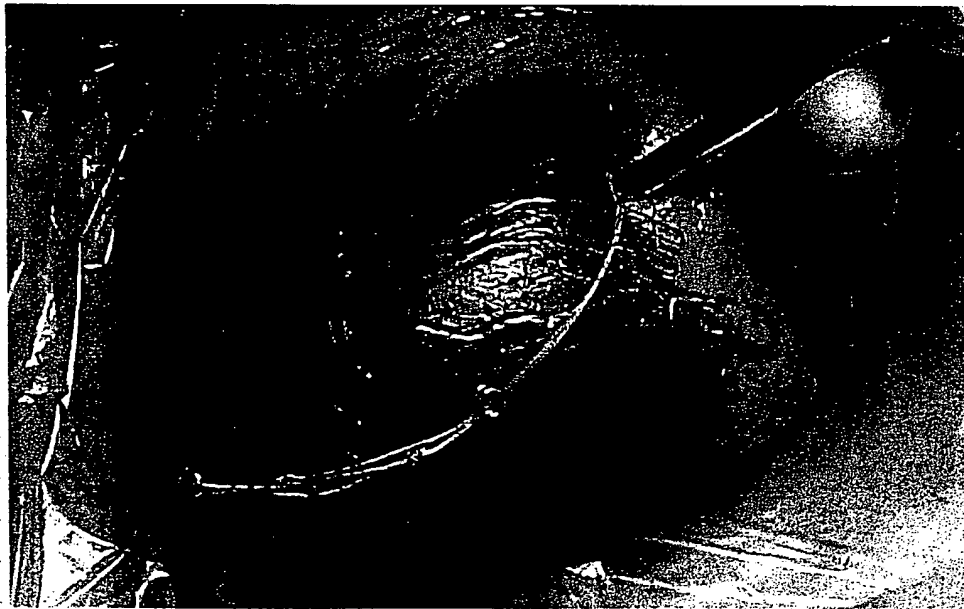


Figure 5: The pattern may then follow the base of the heart toward the septum.

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Ronald H. G. 12/13/99

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Diane Carter  
12/15/99



## CARDIAC HARNESS PATTERNS CONTINUED

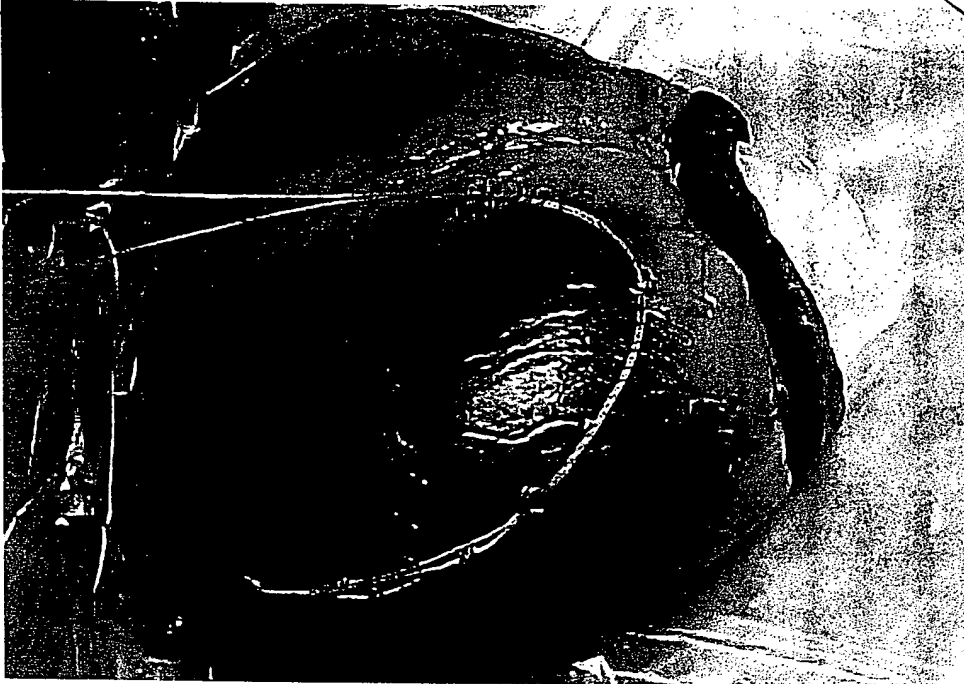


Figure 6: The pattern may then run along the ventricular septum, back towards the apex.

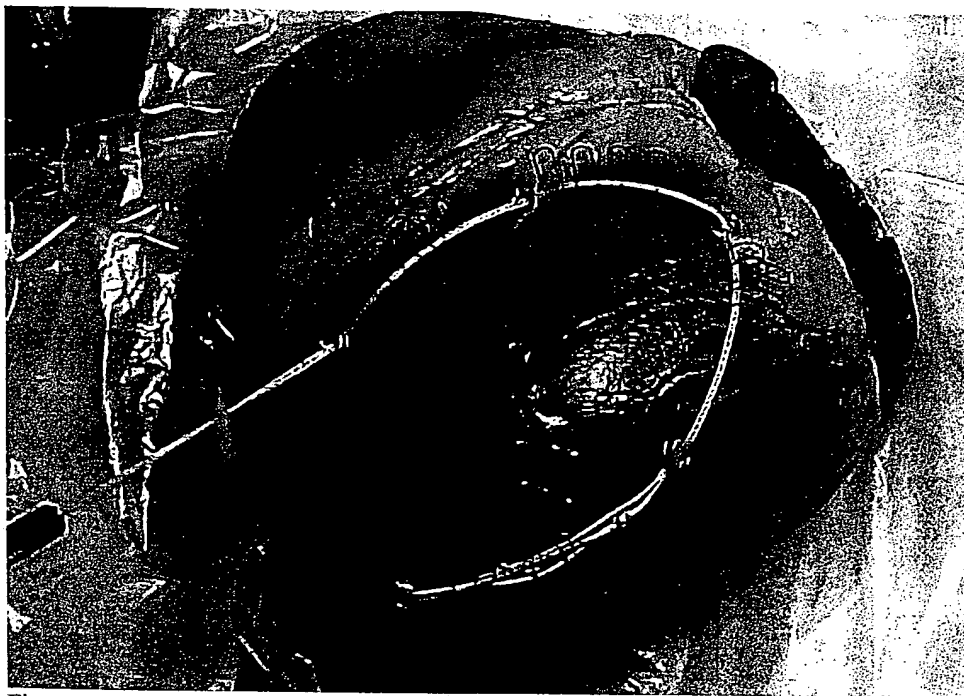


Figure 7: Anchors may have reinforcement if anchored into the septum.

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*David H. Jones* 12/12/99

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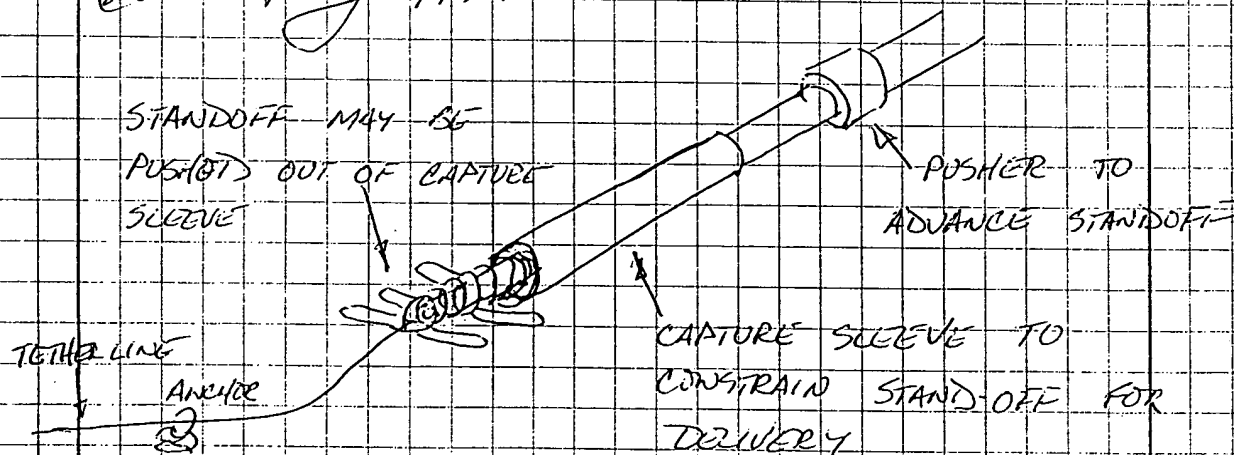
*David H. Jones*  
12/12/99

## CARDIAC HARNESS PATTERNS CONTINUED



Figure 8: The tether line may be terminated at a common anchor, or connected to a power source.

*Daniel H. G. 12/13/99*



*Daniel H. G. 12/13/99*

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*Mike C. 12/13/99*

# CARDIAC HARNESS WITH ACTIVE ASSIST (AUTOLOGOUS)

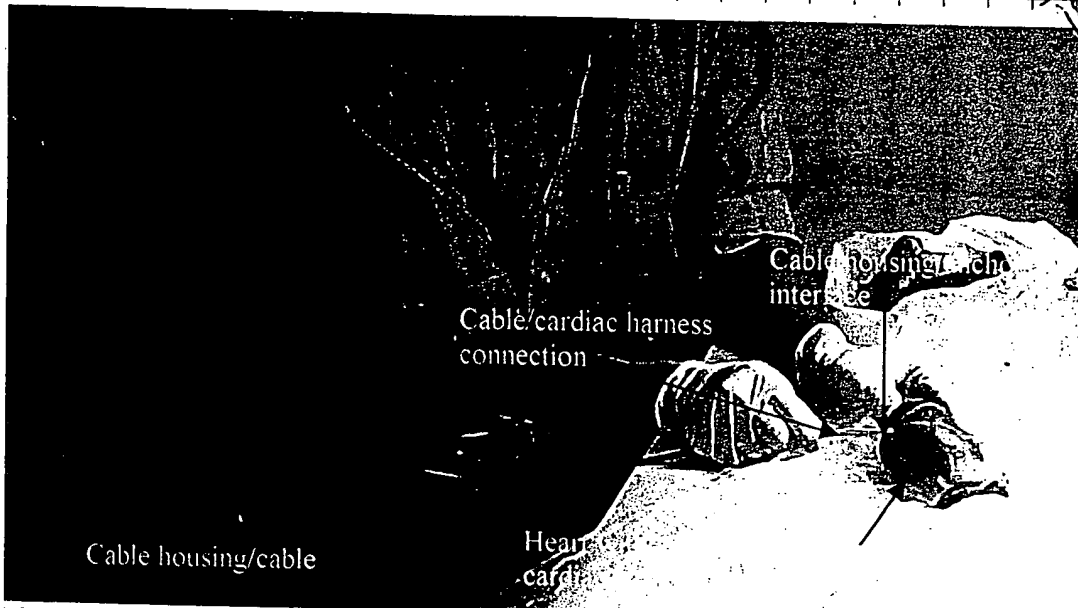


Figure 1: Active cardiac harness powered by bicep contraction.

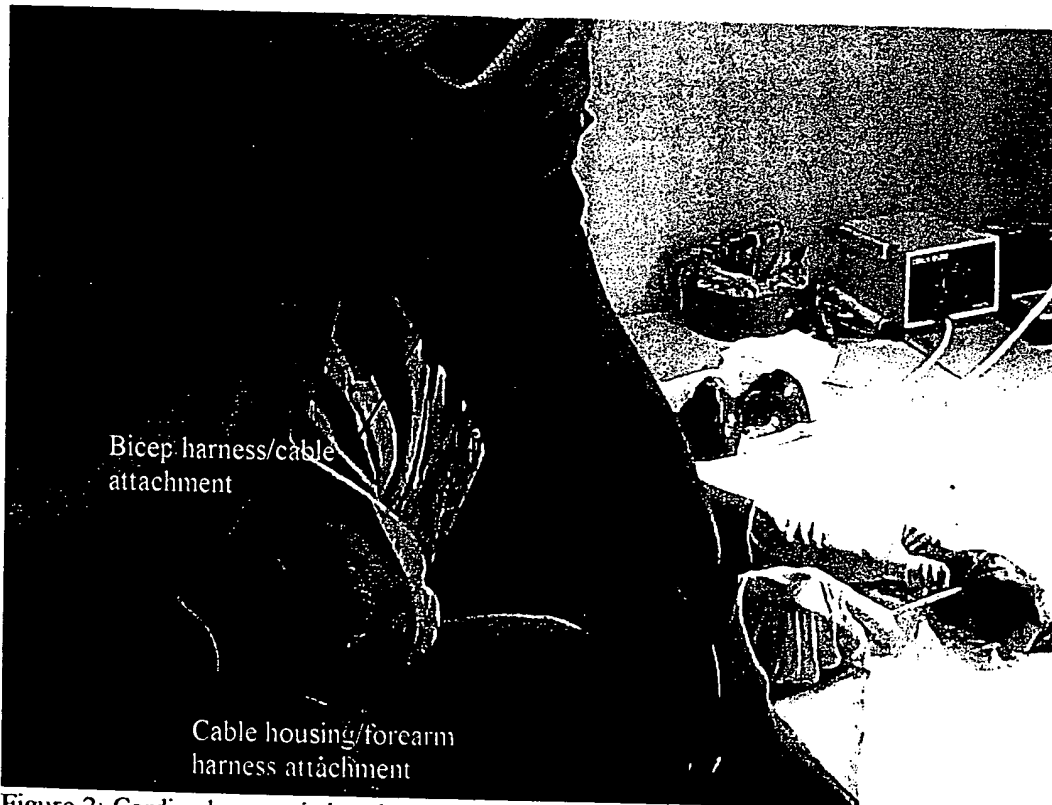


Figure 2: Cardiac harness is in relaxed (slack) state when forearm is extended.

Handwritten signature: *Handwritten signature* 12/13/89

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UNDERSOOD

Handwritten signature: *Handwritten signature* 12/18/89

## ACTIVE ASSIST HARNESS - CONTINUED

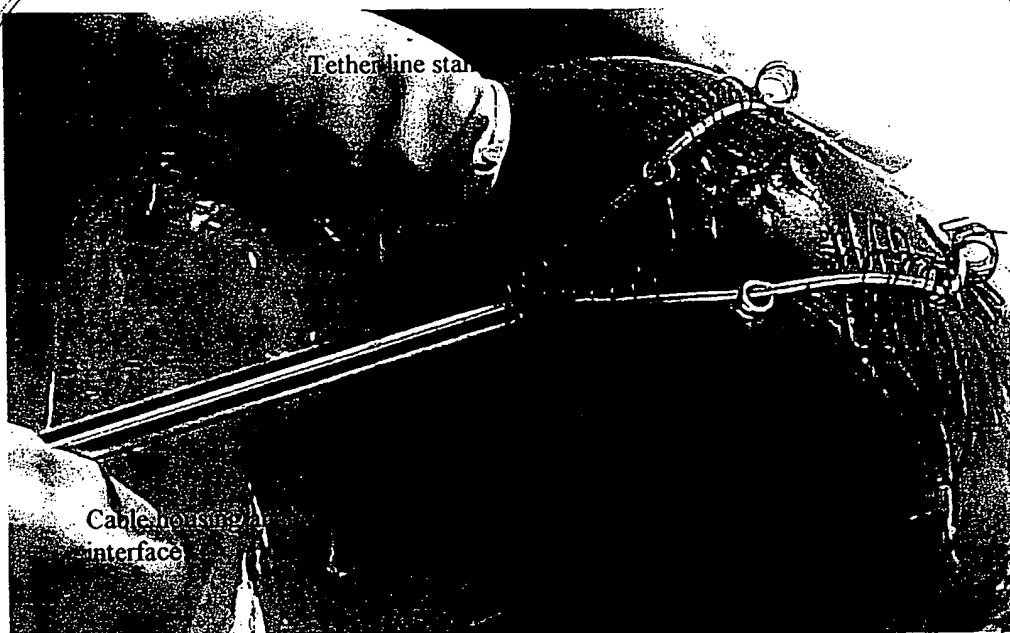


Figure 3: Cardiac harness is slack (end diastolic) state.



Figure 4: Bicep in flexed position, pulls on the cable to activate the cardiac harness.

David H. G. 12/13/99

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↓  
UNDERSTOOD

David H. G. 12/19/99

## ACTIVE ASSIST HARNESS CONTINUED



Figure 5: Cardiac harness tensioned by bicep flexure, compresses left ventricle by up to one centimeter.



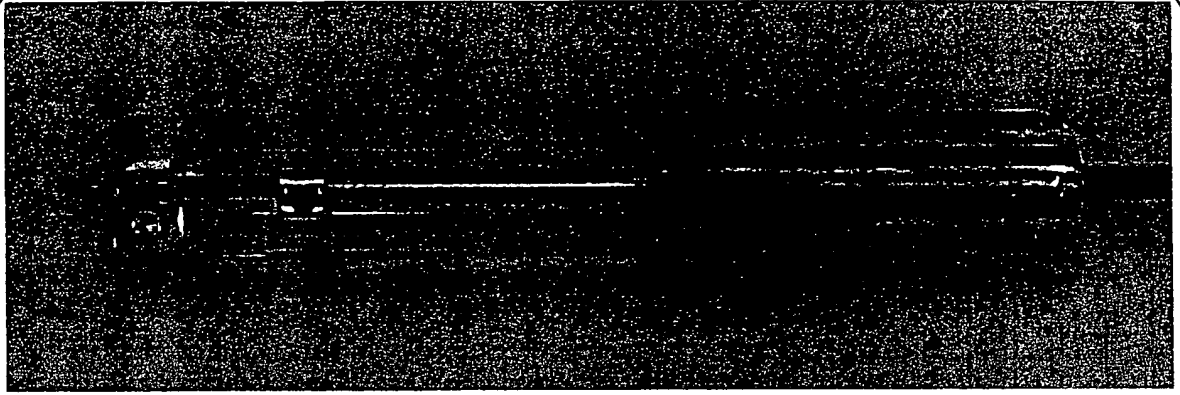
Figure 6: The diaphragm harness was also able to show approximately 0.5 to 1.0 centimeters of left ventricular contraction with expansion due to breathing.

Paul J. G. 12/13/99

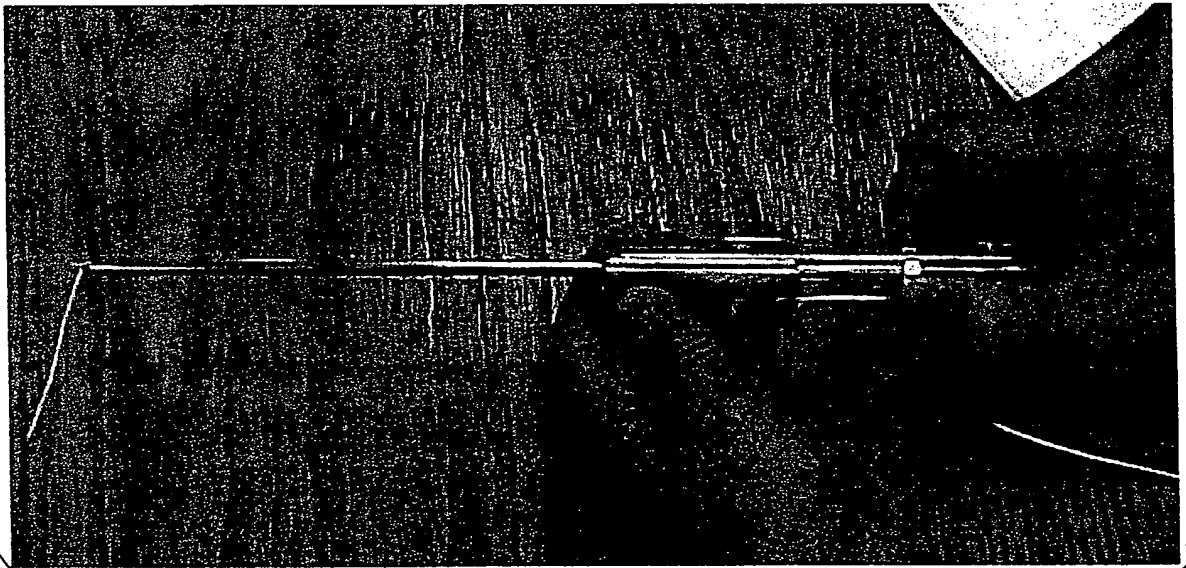
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UNDERSTOOD

Shane P. 12/17/99

## COIL ANCHOR DELIVERY DEVICE (SEE PAGE 5)



6/5/99 Q42



PROTOTYPE OF COIL ANCHOR DELIVERY SYSTEM  
COMPLETED BY DIETER ~ 10-15-99 SUCCESSFULLY  
DELIVERS SINGLE ANCHORS OVER TETHER LINES

Dieter (H. G.) 12/15/99

ROAD  
UNDERSTOOD

Dieter (H. G.) 12/15/99

## BARBED SHEET METAL ANCHORS

Sheet metal end anchors

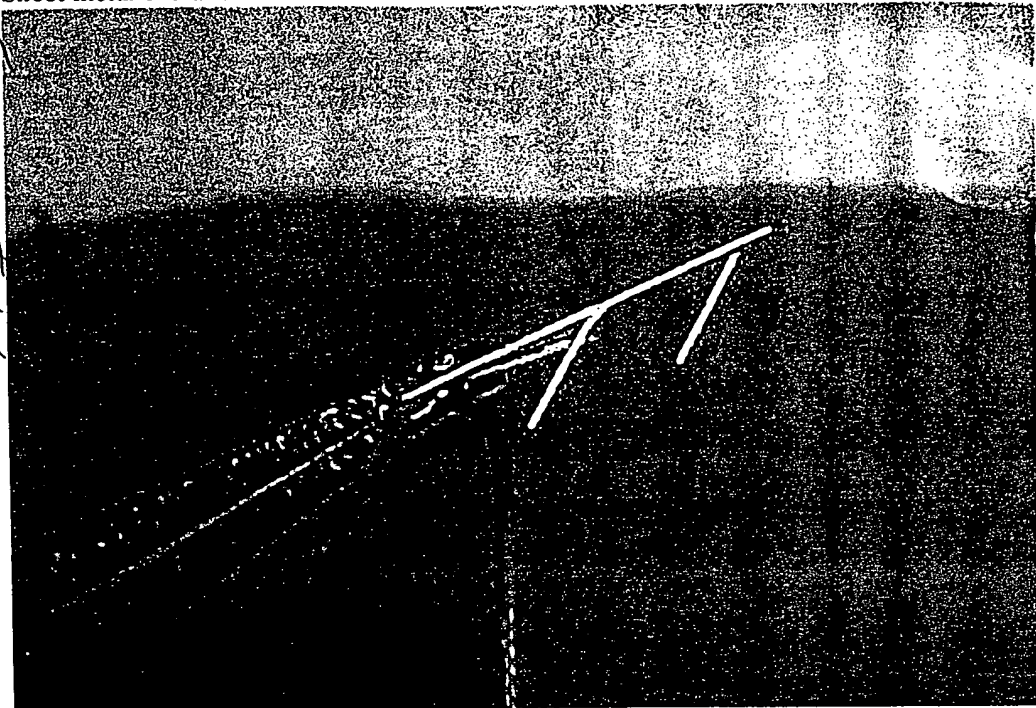


Figure 1: Sheet metal end anchor with tether line. The angle of the barbs, allow the anchor to dig deeper into the tissue with lateral loading. The forces are distributed throughout the anchor and tissue and more barbs may be added for higher loads.



Figure 2: Anchor in being loaded by the tether line through the middle guiding anchors. The sheet metal anchors may distribute and tolerate shear loading better than a coil type anchor, which may tip and may have a higher stress concentration.

David H. G. 12/17/99

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& UNDERSTOOD

David (later)  
12/18/99

## SHEET METAL ANCHORS

D. H. G.  
 12/17/95

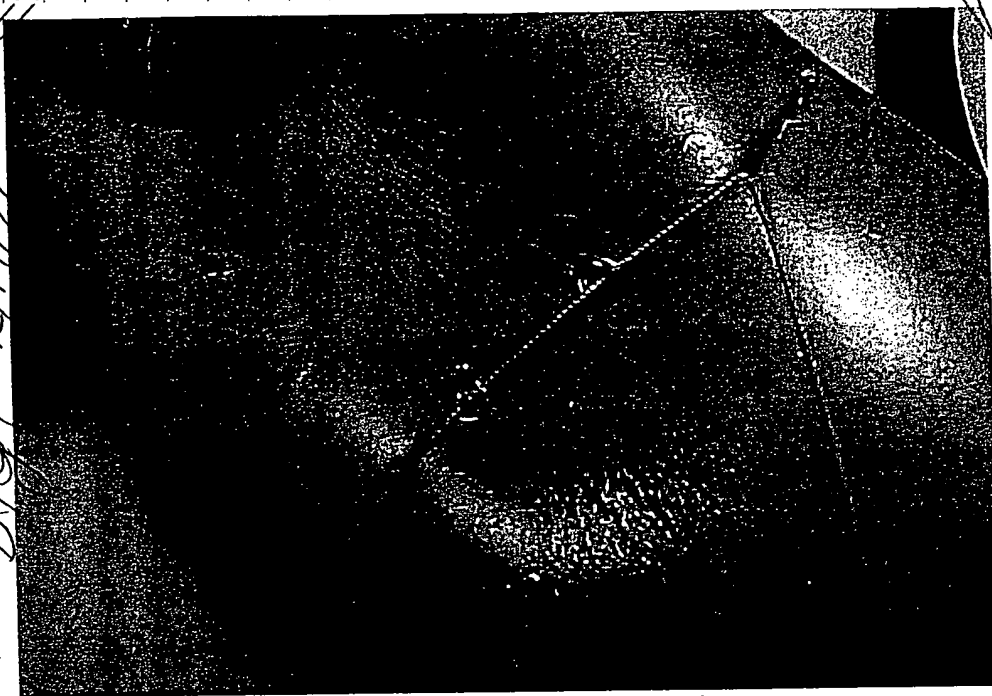


Figure 3: Sheet metal end anchors being tensioned with tether line.

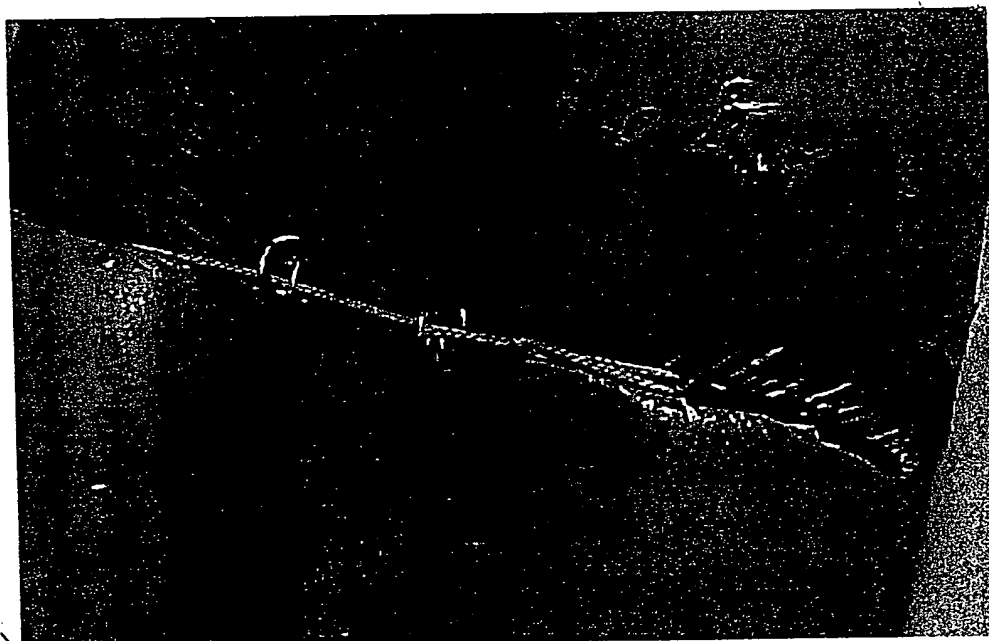


Figure 4: End anchors with extreme loading, buckling the foam model.

Daniel H. G.  
 12/17/95

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Shane Carter  
 12/19/95



SHEET METAL BARBED ANCHORS

Barbed anchors

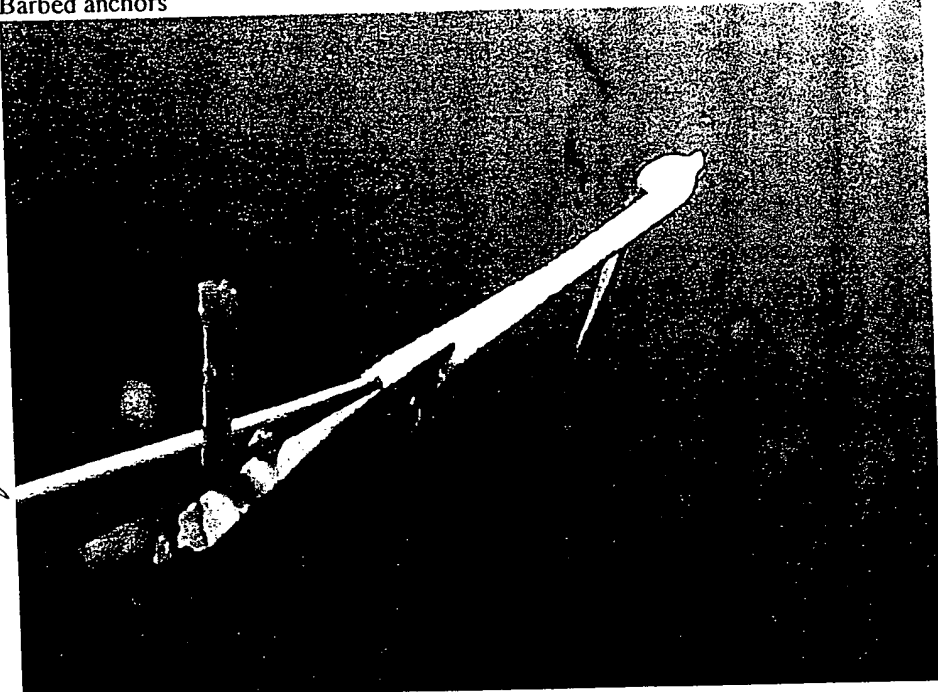


Figure 1: Sheet metal end anchor.

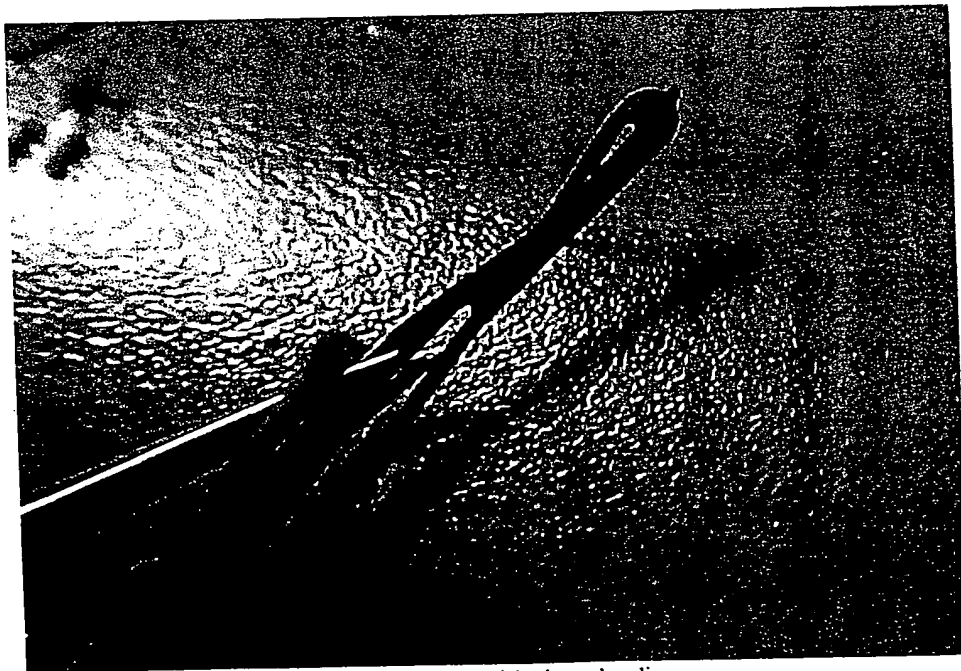


Figure 2: Angle of barbs distribute forces with shear loading.

DHO122099

12/21/99

READS & UNDERSTOOD

Mark Carter

1/17/00

BARBED ANCHORS

DHO 122099

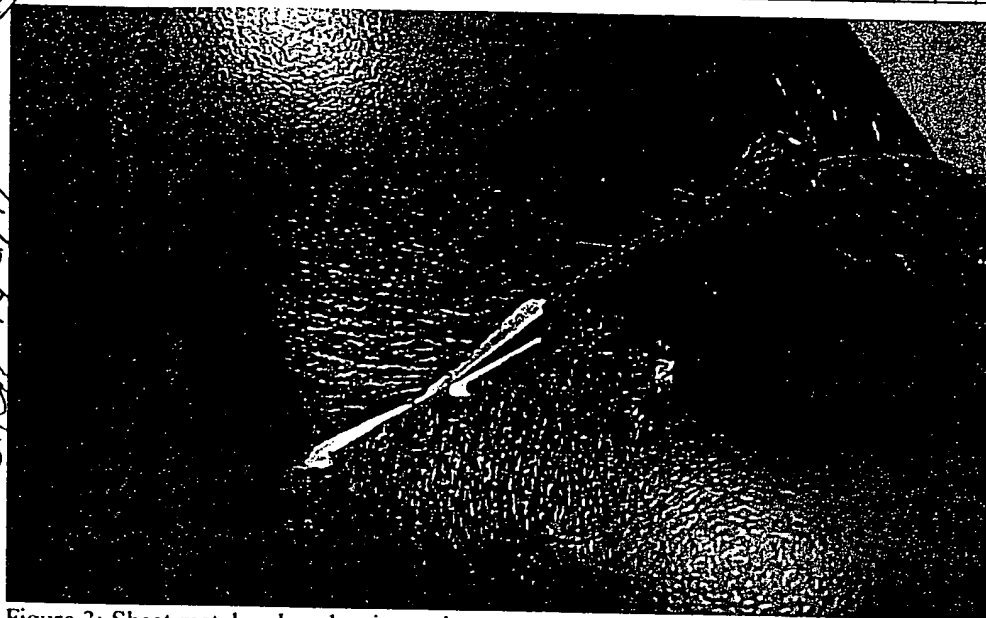


Figure 3: Sheet metal end anchor in tension.

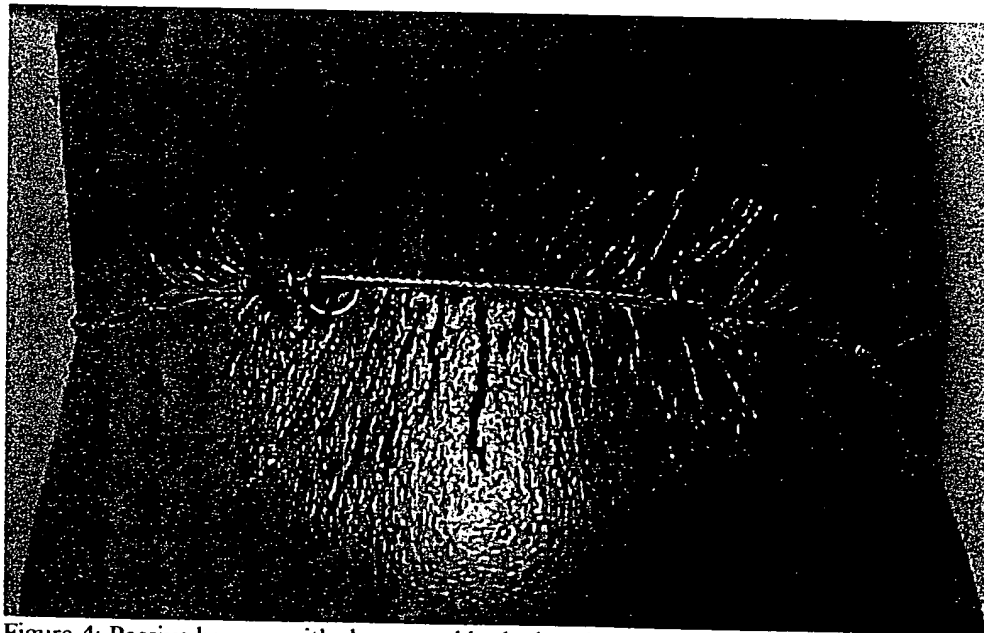


Figure 4: Passive harness with sheet metal barbed anchors and guiding coil anchors.

DHO122099

James J. G.

12/21/99

READ

+ UNDESIGNED

Steve Carter, 1/17/00

## CONICAL ANCHORS

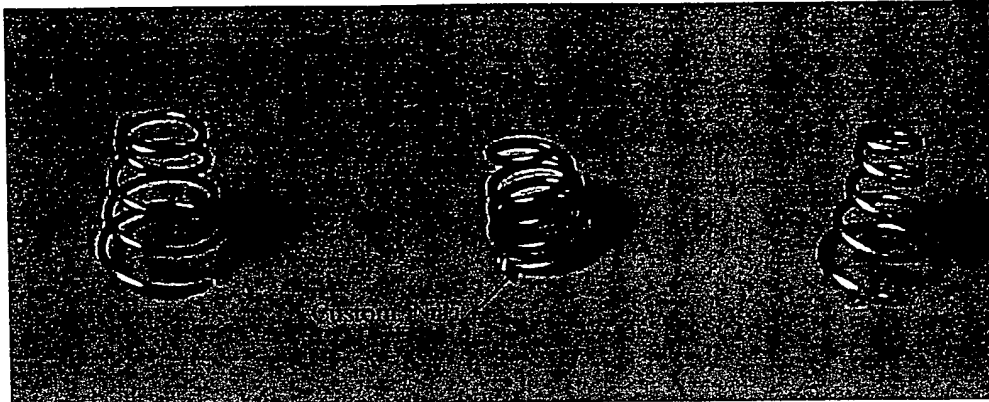


Figure 1: Conical anchors (2 spring steel and 1 Nitinol).

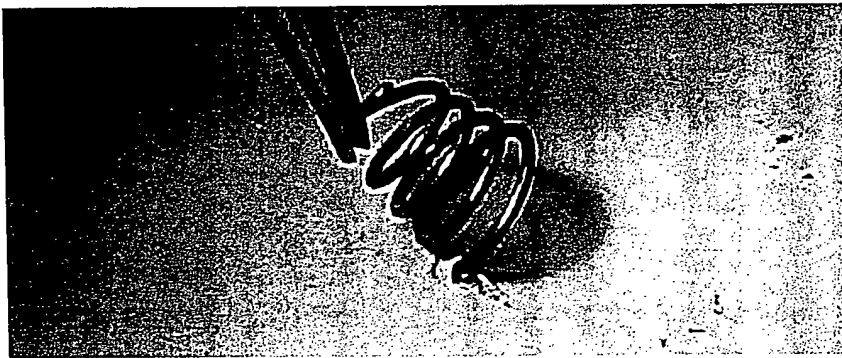


Figure 2: 20 threads per inch Nitinol reverse tapered anchor, wound on fixture.

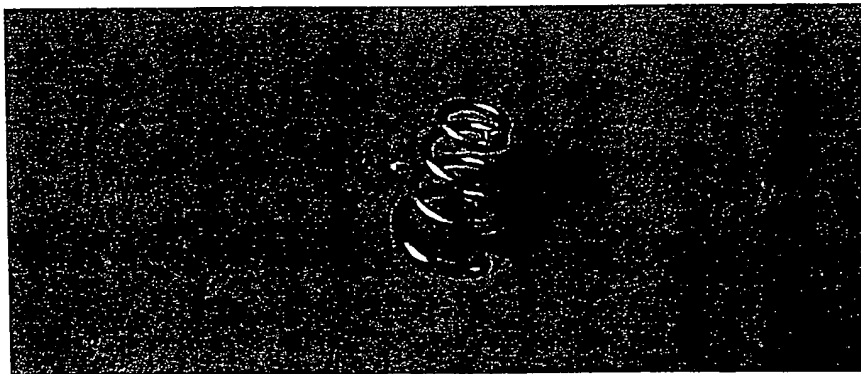


Figure 3: Spring steel tapered anchor easily advances into foam model, but does not collapse down into capture tube.

## CONICAL ANCHORS

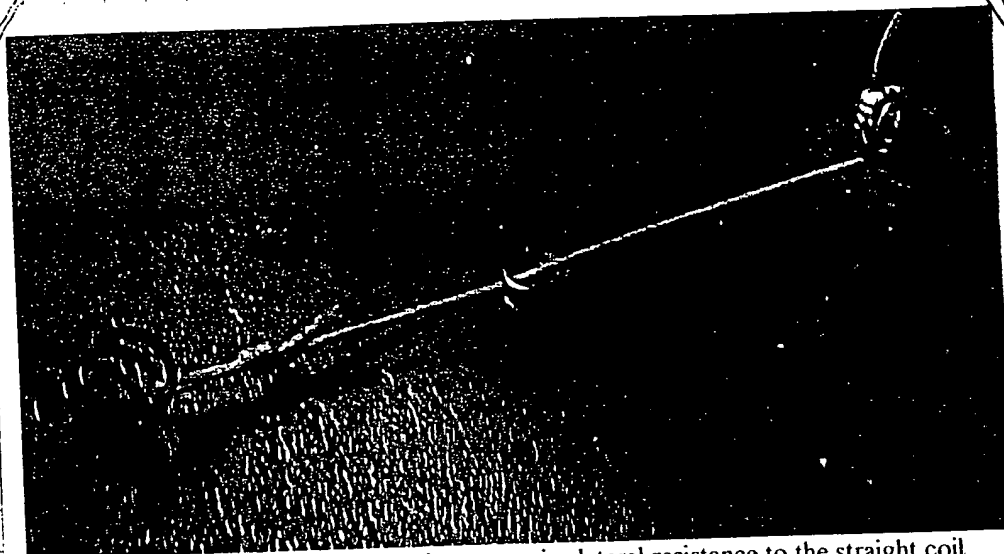


Figure 4: Conical anchors appear to have superior lateral resistance to the straight coil anchors.

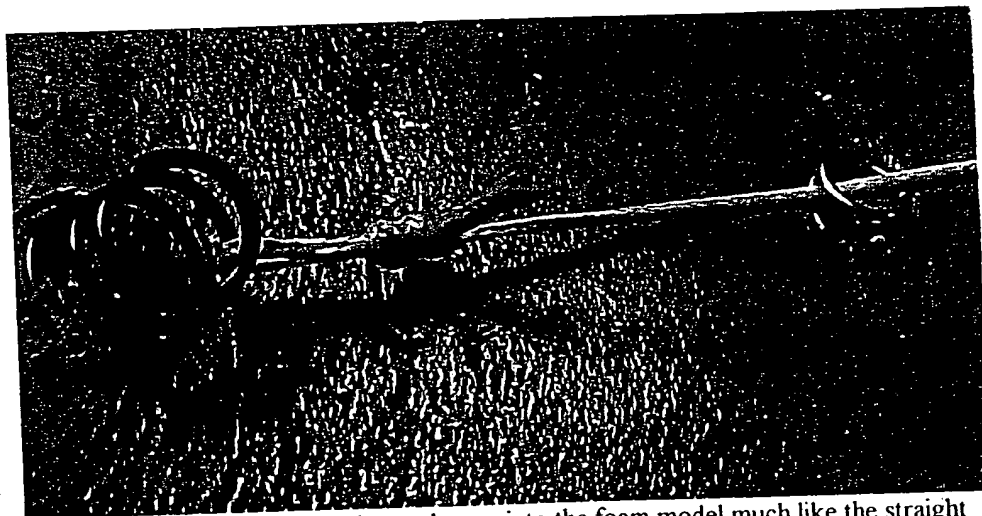


Figure 5: The spring steel anchors advance into the foam model much like the straight coil counter parts, but the nitinol anchors appear to flexible to drive into the foam mode cleanly. The nitinol conical anchor does not easily self thread into the foam, the coils deflect with the resistance of the foam.

DHO122199

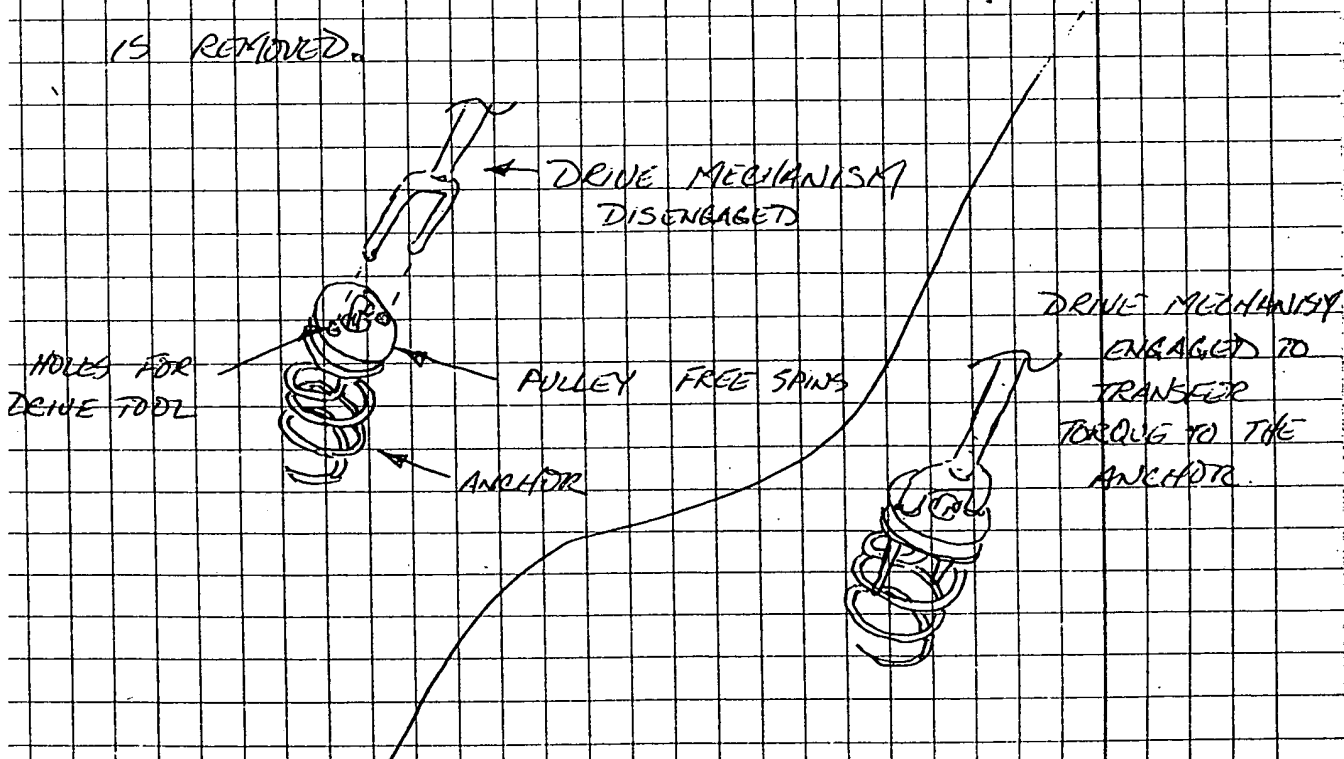
David G. 12/21/99

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Shane Carter  
1/17/00

## ANCHORS WITH PULLEYS

TO ASSIST IN REDUCING FRICTIONAL FORCES WITHIN THE HARNESS SYSTEM, SOME OF THE MIDDLE ANCHORS MAY WANT TO HAVE PULLEYS MOUNTED ON THE TOP SIDE OF THE ANCHOR TO ALLOW THE TETHER LINE TO MOVE FREELY RELATIVE TO THE ANCHOR. THE PULLEY MAY HAVE HOLES OR SLOTS THROUGH THE DISK PORTION TO ALLOW TORQUE TRANSFER TO THE ANCHOR FOR DELIVERY, BUT ALLOW THE PULLEY TO FREEWHEEL AFTER THE DRIVE TOOL IS REMOVED.



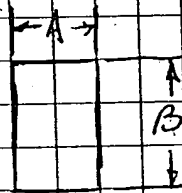
Paul A. G. 12-22-99

READY UNIVERSITY

Paul Carter  
1/17/00

## ELECTROPOLISH LASERCUT COILS (12-16-99)

LASERCUT STAINLESS STEEL COIL ANCHORS WERE TAKEN TO AULBRITZ TO ROUND OFF THE SHARP CORNERS OF THE CUT PARTS VIA MORE AGGRESSIVE ELECTROPOLISHING. DAVE MORTENSON HAD RAUDER WORK WITH ME TO DEVELOP THE POLISHING PROCESS.



		VOLTAGE	CURRENT	TIME
	#1)	7.5-8V	10A	3 MIN
	#2)	7.5-8V	10A	3+3 MIN
CROSS SECTION	#3)	10V	20A	2 MIN
	#4)	10V	20A	3 MIN

PARTS	A DIM	B DIM	AREA
I RAW COIL	.015"	.023"	.00035 in <sup>2</sup>
II FIRST PASS #1 23min	.014	.022	.00031 in <sup>2</sup>
III #2	.007-.010	.015-.016	.00011-.00016 in <sup>2</sup>
IV #4	.010-.011	.017-.018	.00017-.0002 in <sup>2</sup>

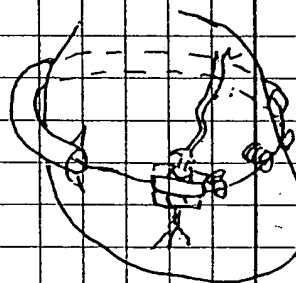
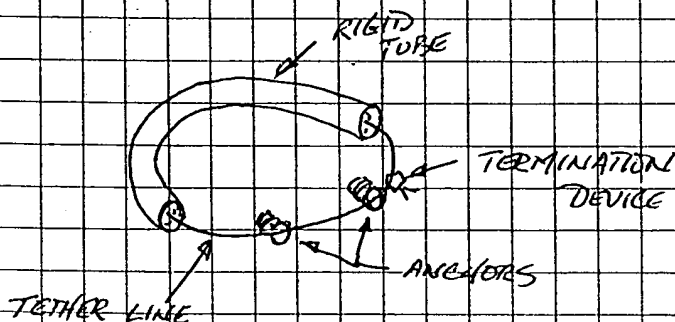
ROUND WIRE = .023"  $\phi$  AREA  $\frac{\pi D^2}{4} = \frac{3.1416 (.023)^2}{4} = .00041$

(David J. G.) 12-22-99

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Dm  
Nicom Center 11/17/00  
Dennis Co.

## RIGID TUBE RIGHT SIDE SUPPORT

THERE MAY BE ADVANTAGES TO REDUCING WALL STRESS BY USING A COMPLETE LOOP HARNESS AROUND THE ENTIRE HEART (SEE PAGE 16). THE DISADVANTAGE IS THAT THE COMPLETE LOOP HARNESS MAY CONSTRICT AND RESTRICT THE RIGHT VENTRICLE IN ADDITION TO THE LEFT VENTRICLE. A METHOD TO ISOLATE THE TETHER LINE FROM THE RIGHT VENTRICLE IS TO HAVE A CURVED <sup>DRD 12-21-98</sup> RIGID TUBE RUNNING AROUND THE BACK, OR RIGHT SIDE OF THE HEART (L. LAV 12/21/99). THE RIGID TUBE WOULD ALLOW EASY MOVEMENT OF THE TETHER LINE AND ELIMINATE OR REDUCE THE RESULTANT - FORCE LOADING ON THE ANCHORS OF THE LEFT VENTRICLE.



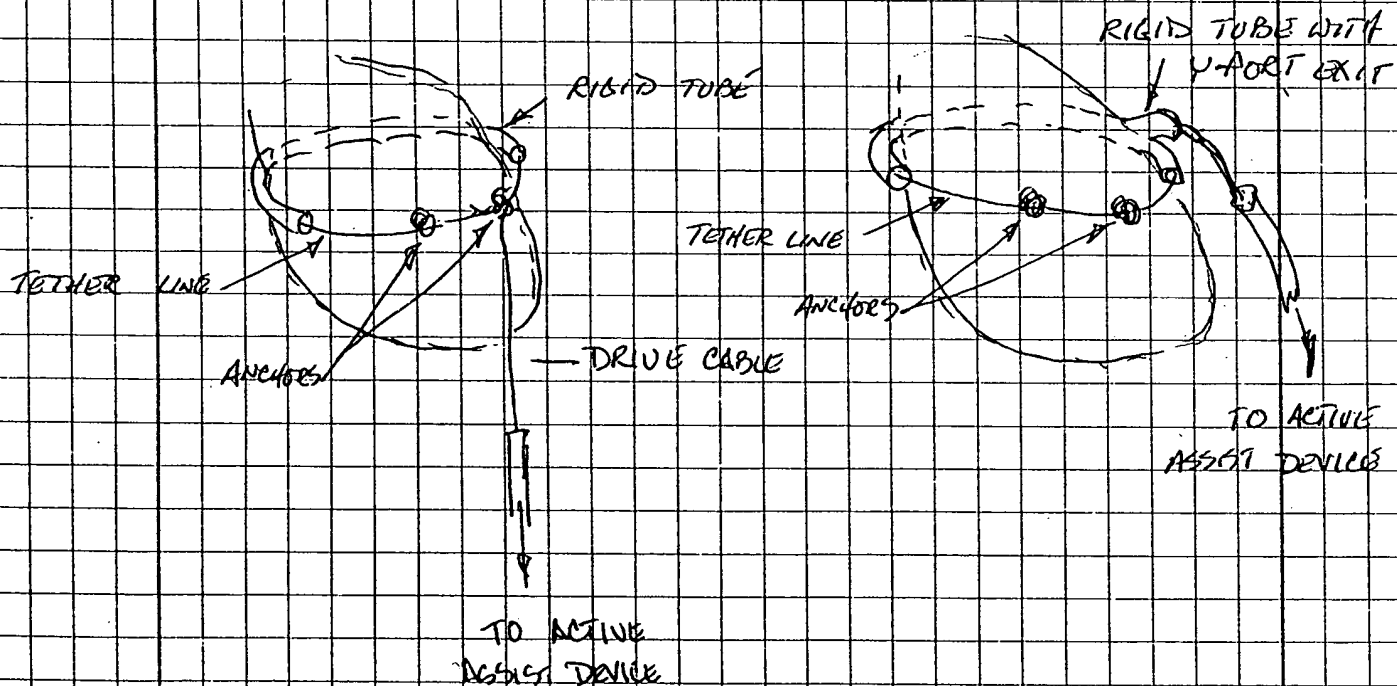
DRD 12-21-98  
12/24/99

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DRD 12-21-98  
1/17/00

## RIGID TUBE WITH ACTIVE HARNESS

THE RIGID TUBE AROUND THE BACK SIDE OF THE HEART MAY BE USED WITH AN ACTIVE HARNESS AS WELL AS WITH THE PASSIVE HARNESS. THE ACTIVE HARNESS MAY BE DRIVEN FROM ONE OF THE ANCHOR POINTS, OR MAY BE DRIVEN FROM A "Y" JOINT OF THE RIGID TUBE. WHEN DRIVEN FROM WITHIN THE CAPTURE TUBE, THE 'PULL' OUT FORCE OF THE ANCHORS IS MINIMIZED.



Daniel A. G. 1-3-00

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1/17/00



## ANCHOR PULL FORCE CHARACTERIZATION

	DIMENSIONS DIA, LENGTH WIRE DIA IN INCHES	STRAIGHT PULL FORCE lbf	LATERAL PULL FORCE lbf
1)	.092 X .288 .015 $\phi$	1.2 CORED	1.6 CORED
2)	.092 X .300 .015 $\phi$	1.4 CORED	1.4 CORED
3)	.092 X .296 .015 $\phi$	1.3 CORED	1.4 CORED
4)	.092 X .325 .015 $\phi$	1.4 CORED	1.6 CORED
5)	.123 X .295 .013-.014 $\phi$	1.7 DEFORMED	1.8 DEFORMED FURTHER
6)	.123 X .310 .013-.014 $\phi$	1.8 DEFORMED	1.7 ABOUT THE SAME
7)	.123 X .290 .013-.014 $\phi$	1.5 CORED	1.6 CORED
8)	.123 X .230 .013-.014 $\phi$	1.5 CORED	1.7 DEFORMED
9)	.155 X .320 .023 $\phi$	2.0 CORED	2.2 CORED
10)	.155 X .290 .023 $\phi$	1.8 DID NOT CORE	2.5 CORED
11)	.154 X .330 .023 $\phi$	2.4 CORED	2.6 CORED
12)	.154 X .325 .023 $\phi$	2.3 CORED	2.2 CORED

Samuel H. Co 1/12/00

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Dave Carter  
1/17/00

ANCHOR	PULL FORCE CHARACTERIZATION			
	DIMENSION WIRE DIA IN INCHES	DIA, LENGTH IN INCHES	STRAIGHT PULL FORCE LBF	LATERAL PULL FORCES LBF
13)	.155 X .320 .023 $\phi$	310 <del>110</del> 1-12-00	2.3 CORRUPT	2.6 CORRUPT
14)	.155 X .312 .023 $\phi$		2.4 CORRUPT	2.3 CORRUPT
15)	.155 X .325 .023 $\phi$		2.4 CORRUPT	2.4 CORRUPT
16)	.154 X .320 .023		2.4 CORRUPT	2.4 CORRUPT

David H. G. 1-12-00

ANCHORS 1-4 STRAIGHT COIL

ANCHOR 5-8 STRAIGHT COIL

ANCHORS 9-12 SOLDERED SINGLE SHOT STRAIGHT COIL

ANCHORS 13-16 MODIFIED CS-1 REVOLVER ANCHOR

DHG 1/12/00

ROBINS + UNDERSTOOD

David H. G.  
1/17/00

# SIX SHOOTER ANCHOR DELIVERY SYSTEM

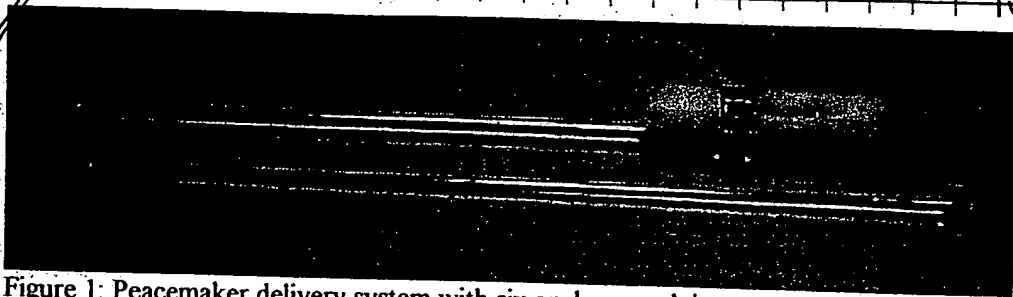


Figure 1: Peacemaker delivery system with six anchor revolving storage magazine and slotted drive mechanism.

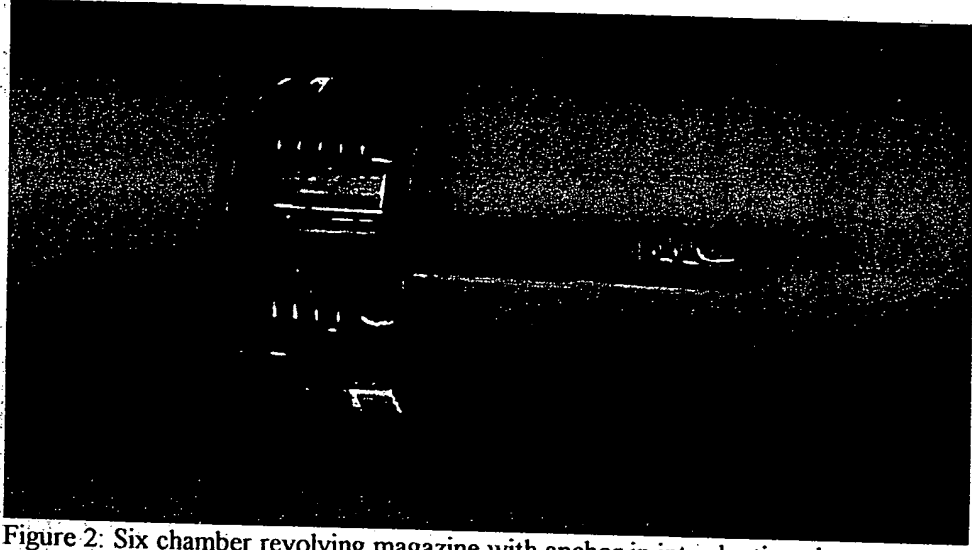


Figure 2: Six chamber revolving magazine with anchor in introduction slot.

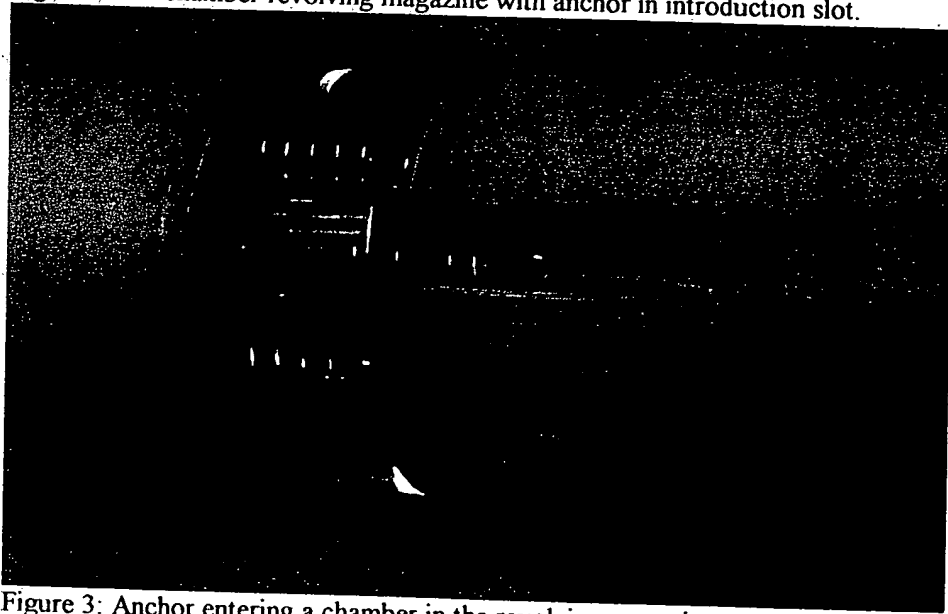


Figure 3: Anchor entering a chamber in the revolving magazine.

*Subj: 11/14/00*

*David H. G. 11/14/00*

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*David H. G. 11/17/00*

## PEACEMAKER DELIVERY SYSTEM - CONT

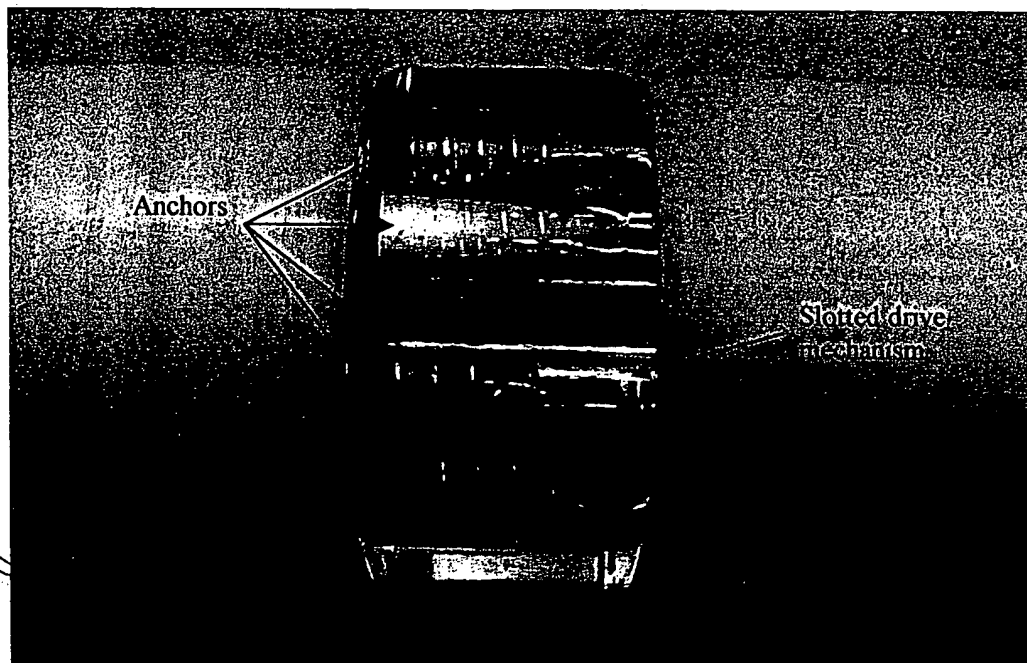


Figure 4: Drive mechanism engaging with the loop end of an anchor in the chamber.

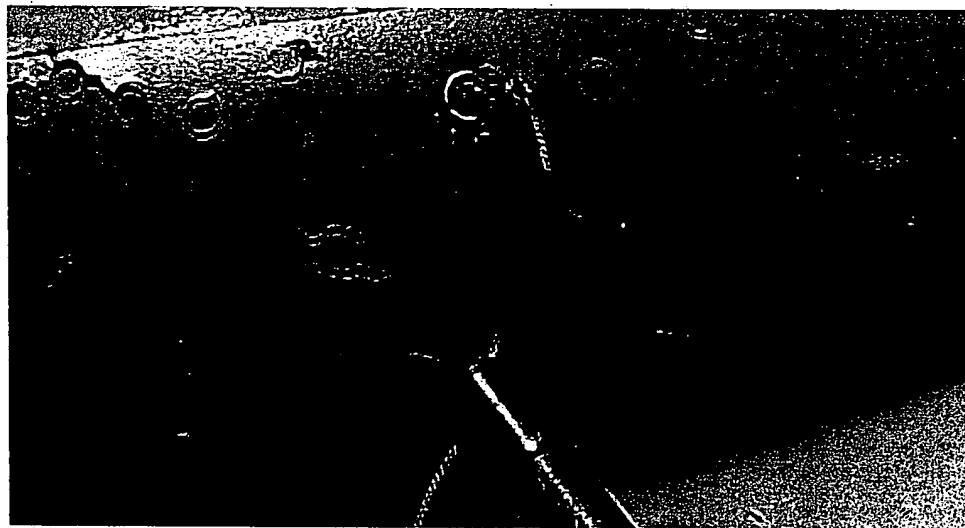


Figure 5: First anchor is driven into the foam model with tetherline fed through a side port in the threaded tip.

David H. G.

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Mike Cox  
1/17/00

## MULTI ANCHOR DELIVERY SYSTEM - CONT

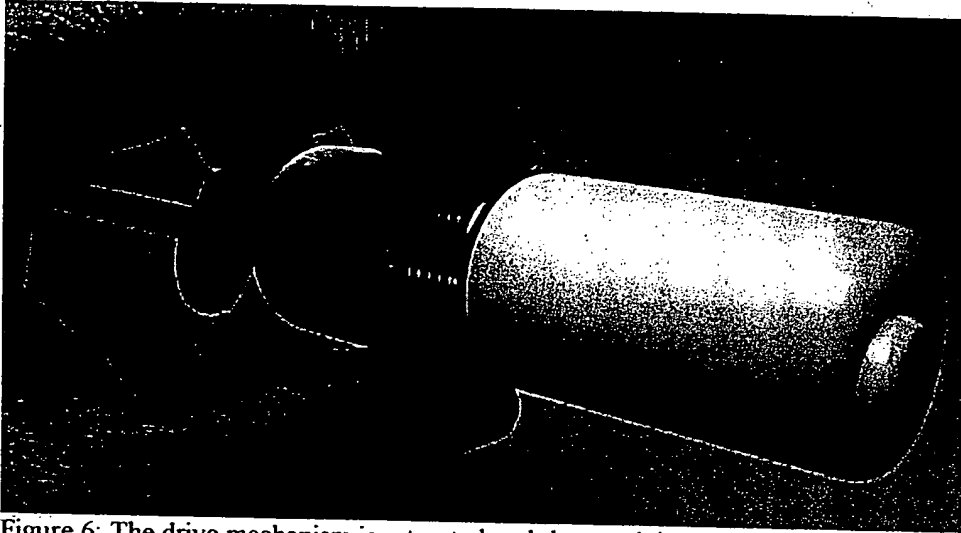


Figure 6: The drive mechanism is retracted and the revolving magazine is rotated to align the next anchor with the anchor delivery bore.

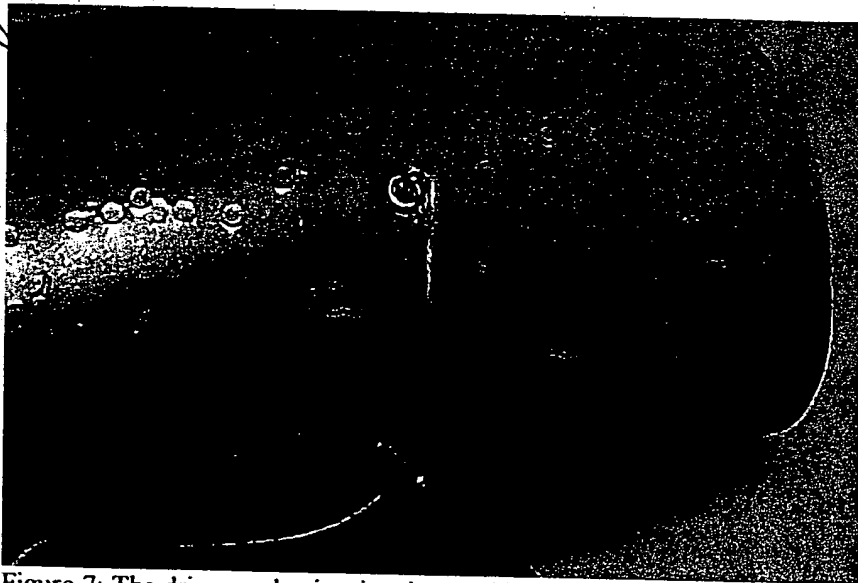


Figure 7: The drive mechanism is reinserted into the delivery system, a next location is identified and the second anchor is delivered into the foam model.

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David Carter 1/17/00

## MULTI ANCHOR DEVIATION SYSTEM



Figure 8: The third anchor is indexed into position and delivered at the next location.



Figure 9: The fourth anchor is indexed into position and the location is identified.

Donald A. G.

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Gene Carter

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11/18/00

PEACEMAKER - CONT



Figure 10: Once the fourth (and final in this case) anchor is inserted, the tetherline is checked to confirm free movement through the anchor loops.

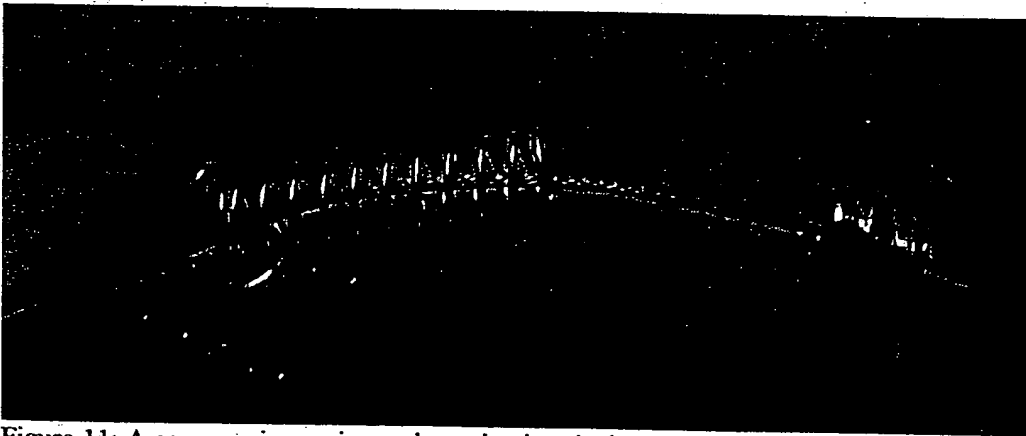


Figure 11: A compression spring and termination device are added to the tetherline for end termination.

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MULTI ANCHOR DEPLOYER - CONT.

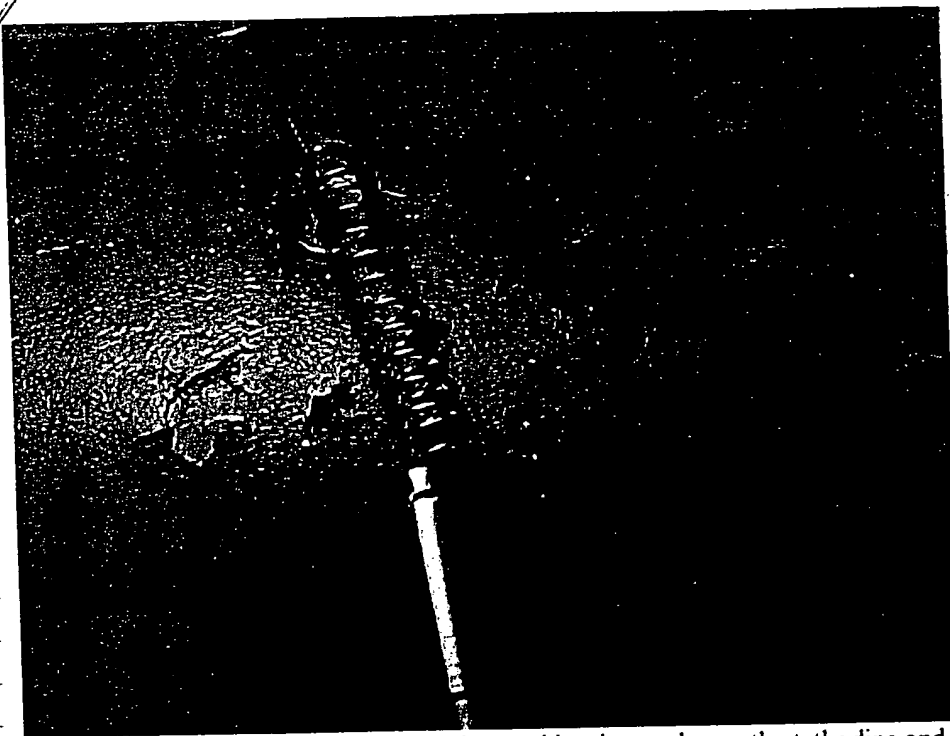


Figure 12: The end termination tightening tool is advanced over the tetherline and engaged with the termination device.

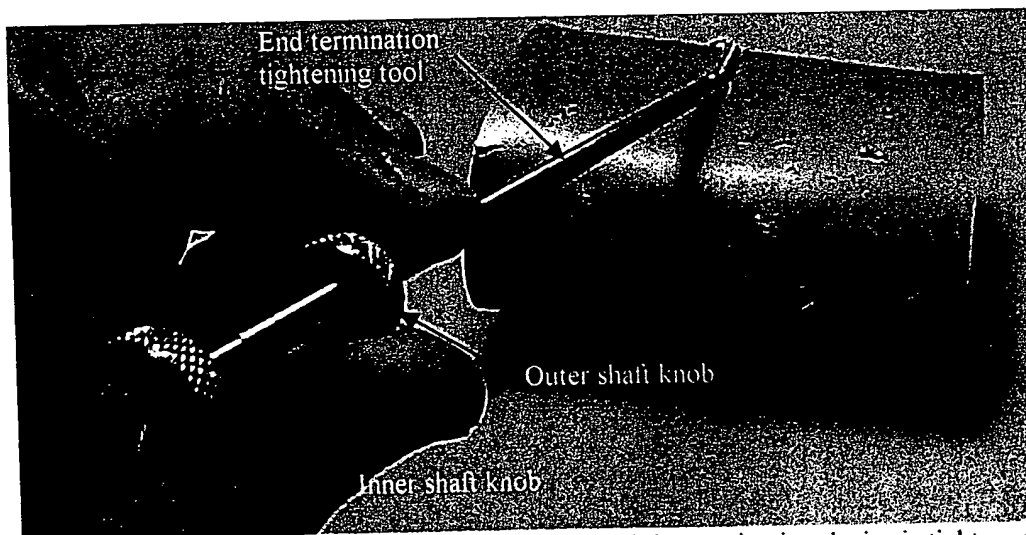


Figure 13: The tension of the tetherline is adjusted and the termination device is tightened by holding the outer shaft knob steady, while turning the inner shaft knob clockwise.

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Gene Carter  
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MULTI ANCHOR DELIVERY - CONT



Figure 14: Harness with compression spring in series will decrease the shock of the tetherline tensioning at end diastole and stored energy in the spring should assist the initial contraction of systole.

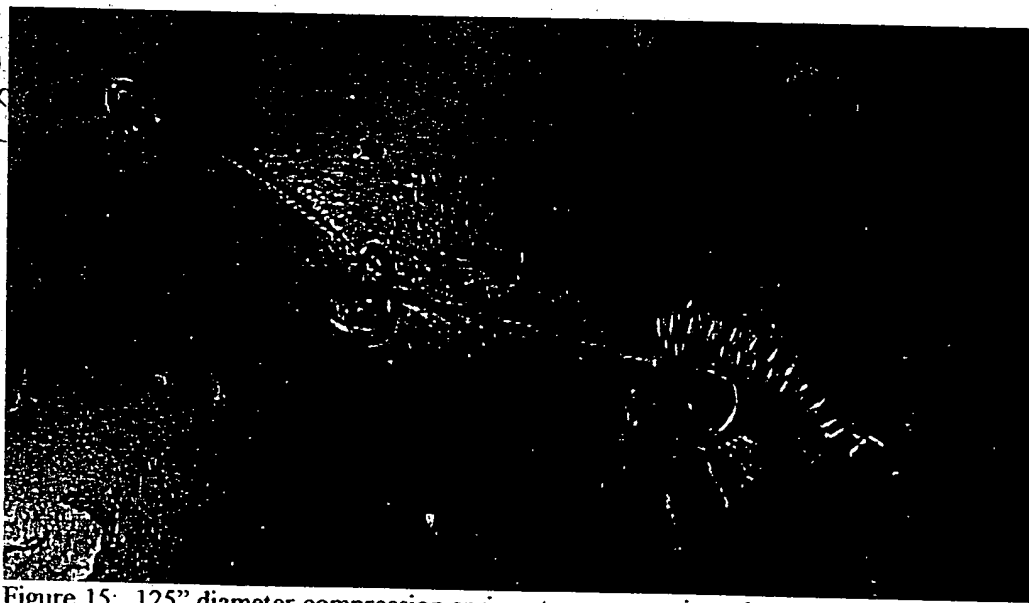


Figure 15: .125" diameter compression spring stores approximately 1 pound of force with 1 centimeter of compression. Note, the end of the .125" diameter compression spring does not seat square with the anchor loop and may corkscrew into the loop.

David H. G. 1-14-00

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Dave Cate  
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## MULTI ANCHOR DUCKY SYSTEM - CONT

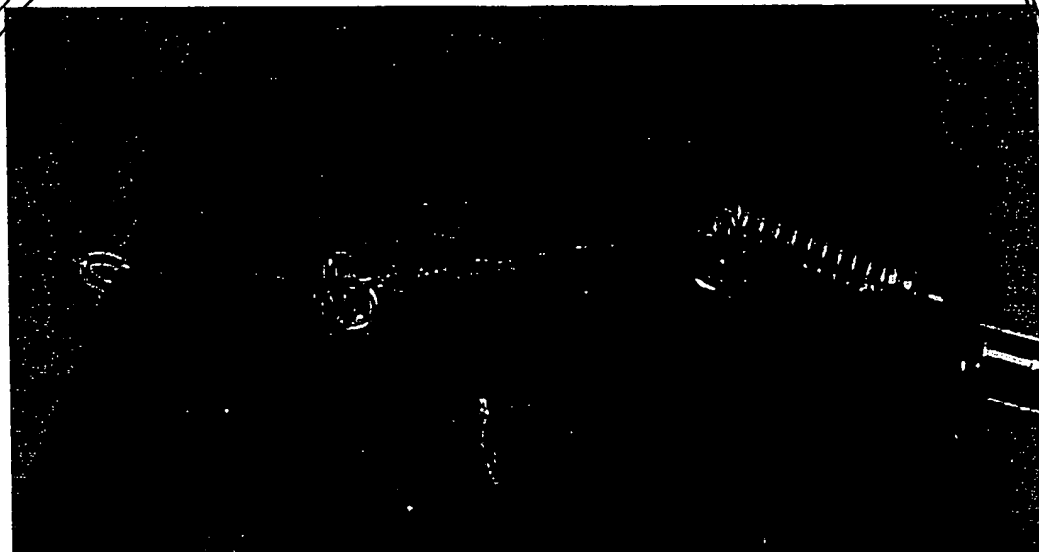


Figure 16: The termination device may also be loosened to readjust the tension in the harness.

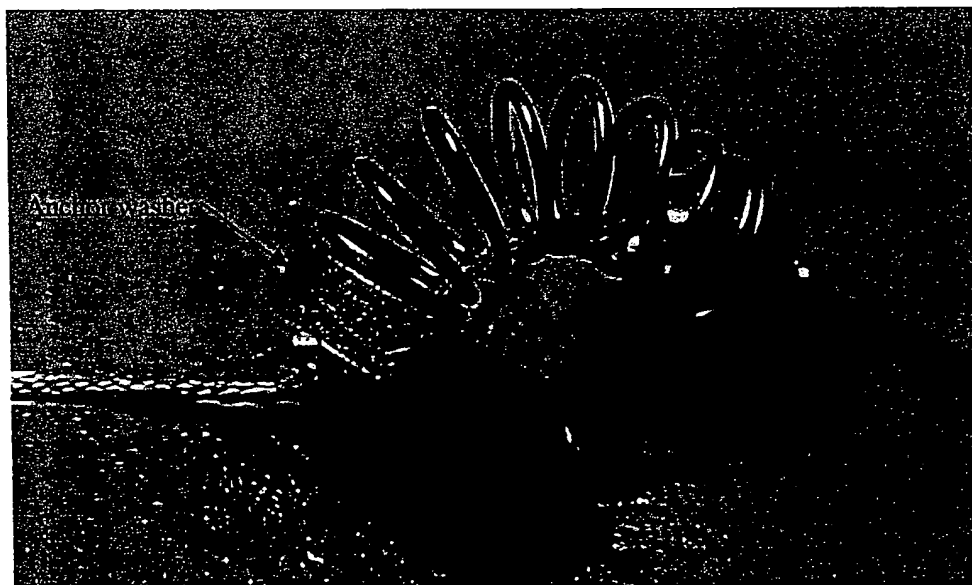


Figure 17: A .156" diameter compression spring with an anchor washer, still curves some with compression. The .156" diameter spring stores approximately 1.2 pounds with 1 centimeter of compression.

*Daniel H. G. 1/14/00*

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*Diane Carter*

1/17/00

## COMPRESSION SPRING IN SERIES

Tether line compression spring in series



Figure 1: Compression spring with machined end caps in tension.



Figure 2: Coil spring still bends when compressed by tension in the tether line. Some type of telescoping shafts (like a shock absorber) may be needed to straighten movement of the spring.

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RIGID RIGHT SIDE TUBE SUPPORT WITH CABLE ACTIVATION

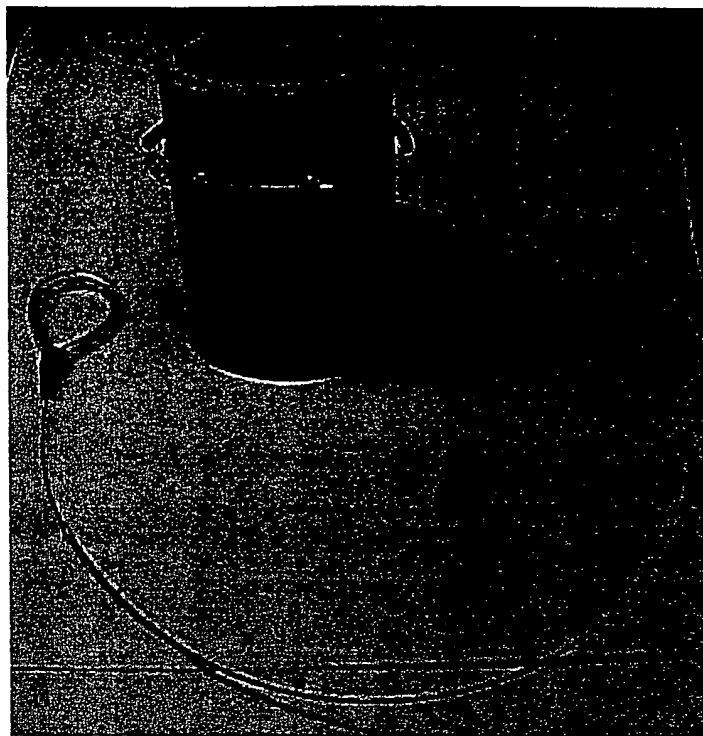


Figure 1: Nitinol wire tether line harness with rigid tube wall support, stand-offs and .042" diameter polyimide/stainless steel reinforced activation cable.

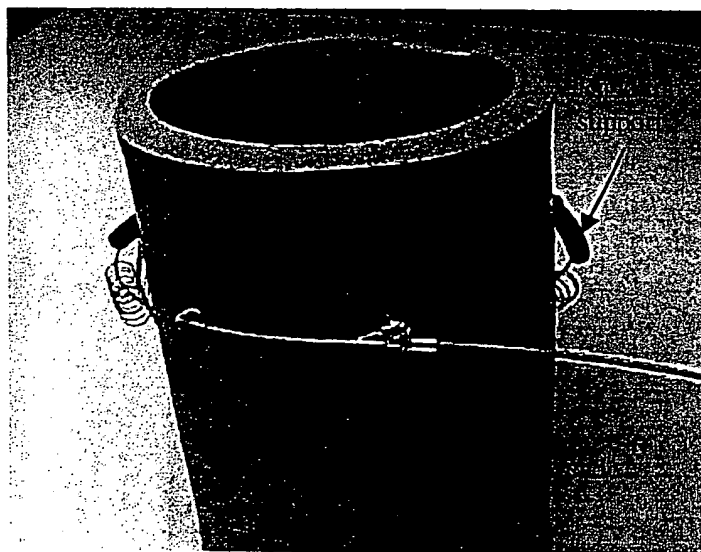


Figure 2: Harness with rigid support tube on the backside of the foam model.

David A. G. 1/24/00

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Mike Carter 2/24/00

RIGID TUBE SUPPORT WITH FOAM MODEL CONT

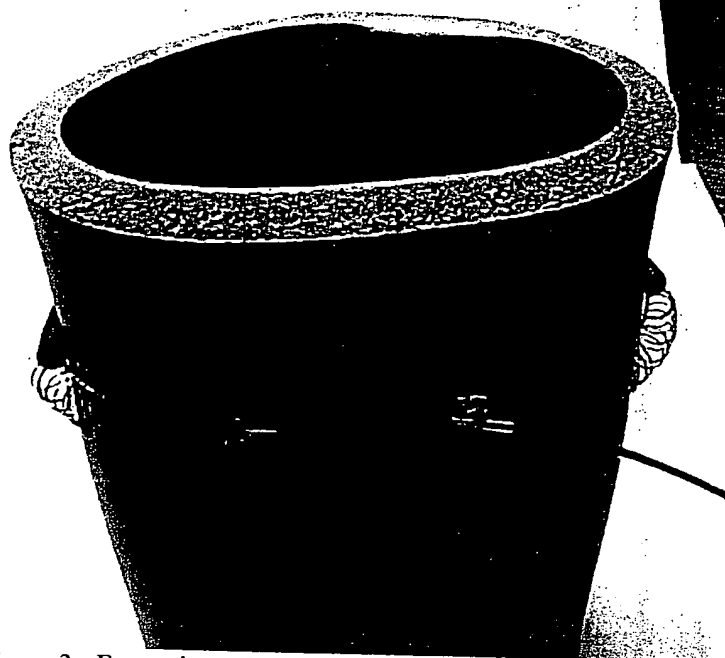


Figure 3: Front view of harness in the tensioned state, pulling in the unsupported wall of the foam model.

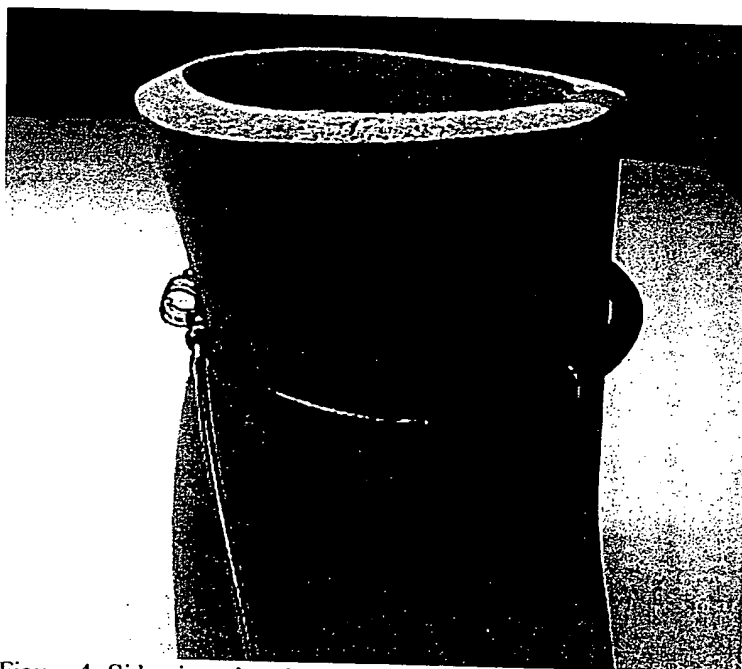


Figure 4: Side view showing the rigid tube side staying more cylindrical and the harness side of the model being compressed.

*Adrian G.* 1/24/00

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*Steve Carter*  
2/20/00

RIGID TUBE SUPPORT - CONT

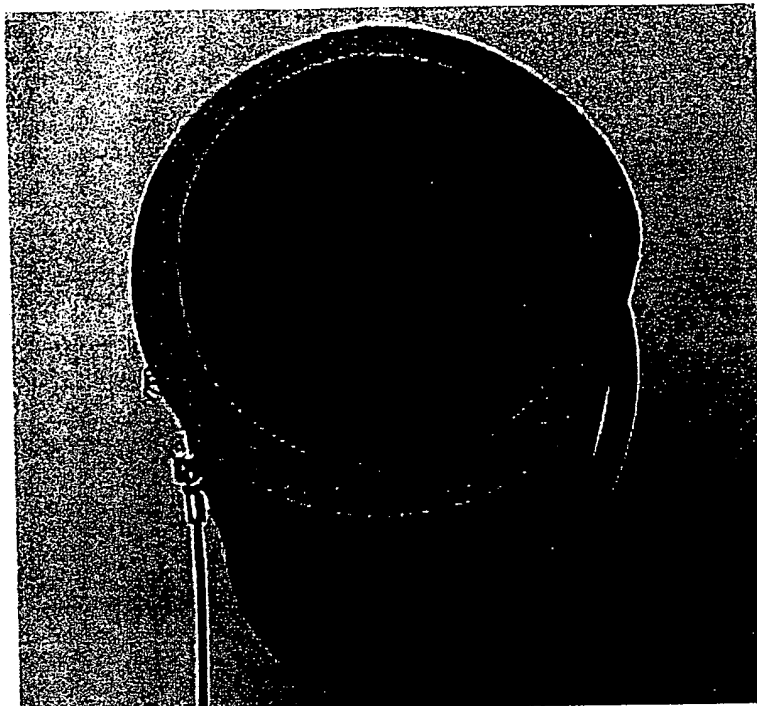


Figure 5: Top view showing cylindrically shaped model with relaxed harness.

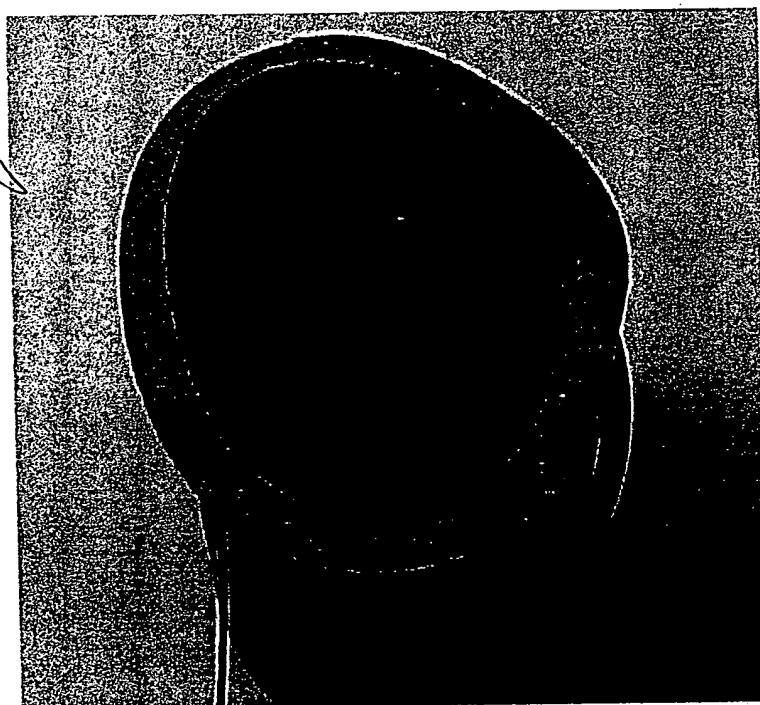


Figure 6: Illustrating more compression on the left side, while the rigid tube side stays more cylindrical and less compressed.

*David G. 1/24/00*

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*David Carter*  
2/21/00

DUAL LINE CENTER PULL CABLE

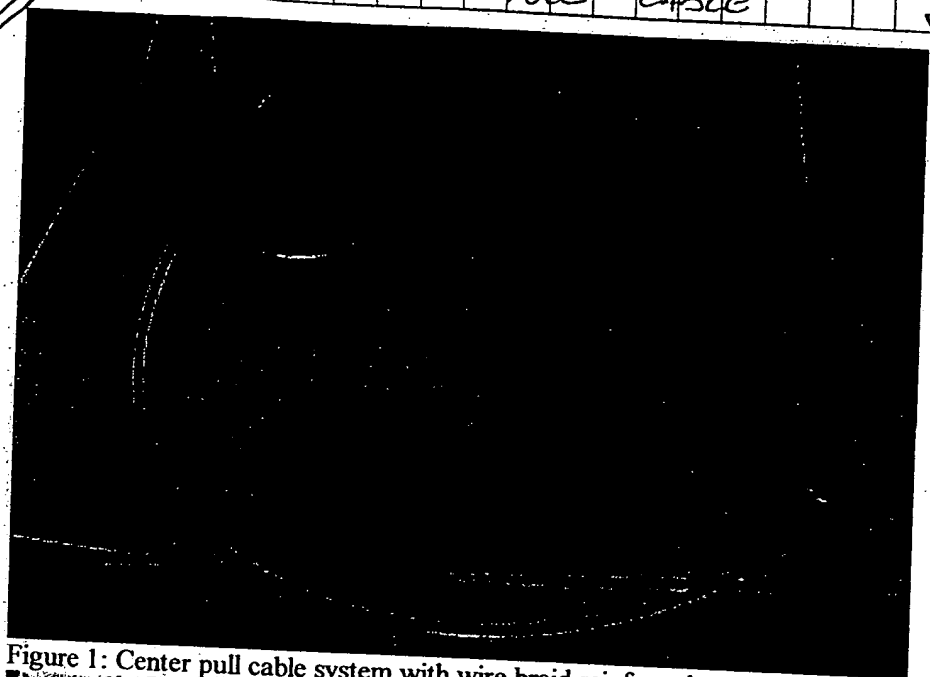


Figure 1: Center pull cable system with wire braid reinforced extruded housing.

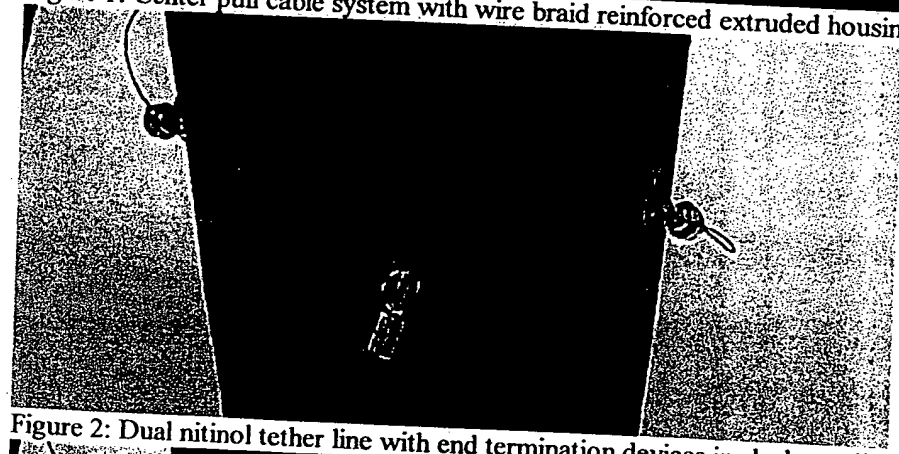


Figure 2: Dual nitinol tether line with end termination devices in slack condition.

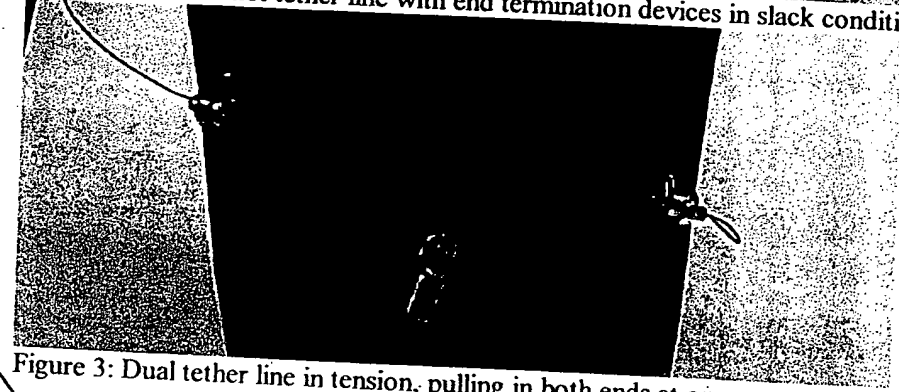


Figure 3: Dual tether line in tension, pulling in both ends at once.

1/25/00

David G.

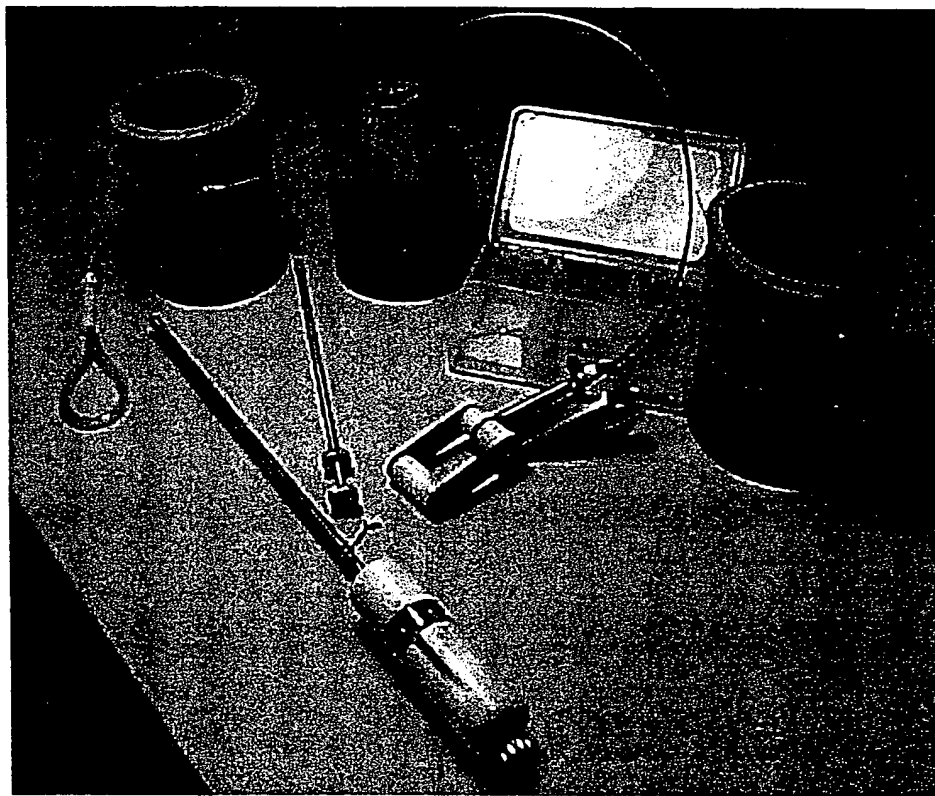
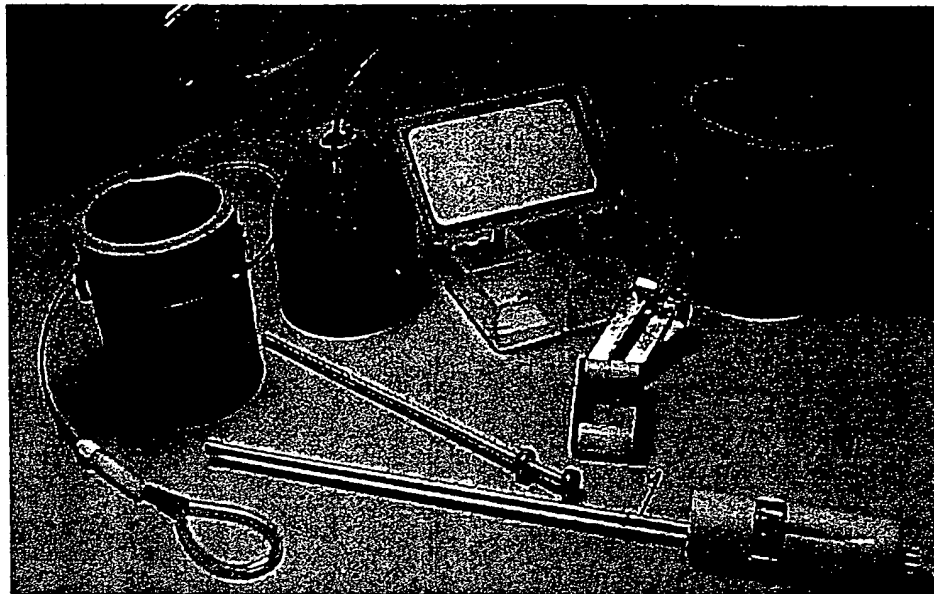
1/25/00

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Don Carter 2/21/00

## DEMONSTRATION MODELS



Active and passive harness models, delivery systems and components shown to Dr. Ray Chiu on 1-31-00, Dr. James Magovern on 1-25-00 and Dr. Larry Stephenson on 1-24-00.

*David H. G.* 1/28/00

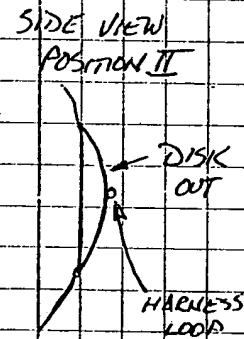
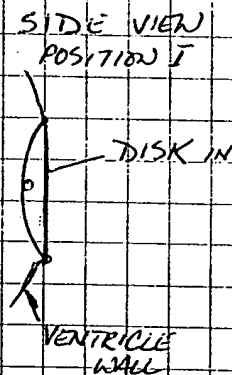
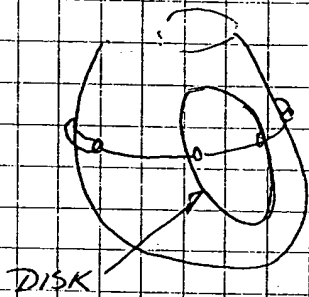
ROADS  
& UNDERSTOOD

*Shane Carter* 2/21/00



# BI-STABLE DISK TO ASSIST LEFT VENTRICULAR CONTRACTION

A BI-STABLE DOMED DISK MAY BE USED TO COMPRESS THE EPICARDIAL SURFACE OF THE LEFT VENTRICLE. THE BI-STABLE CHARACTERISTIC (OIL CAN EFFECT) WOULD USE A HARNESS TO COMPRESS THE DOMED DISK "OVER-CENTER", THEN THE ENERGY OF THE DISK WILL HELP COMPRESS THE OUTSIDE WALL OF THE LEFT VENTRICLE.



DURING DIASTOLIC FILLING, THE PRESSURE FROM THE VENTRICLE WALL DUE TO FILLING, WOULD PUSH THE DOMED DISK BACK OUT TO ITS OUTWARD STABLE CONDITION. THE HARNESS WOULD PULL IN TENSION AGAIN TO REPEAT THE CYCLE.

*Handwritten signature*

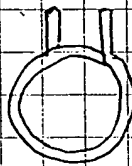
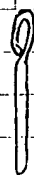
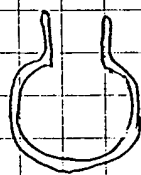
2-7-00

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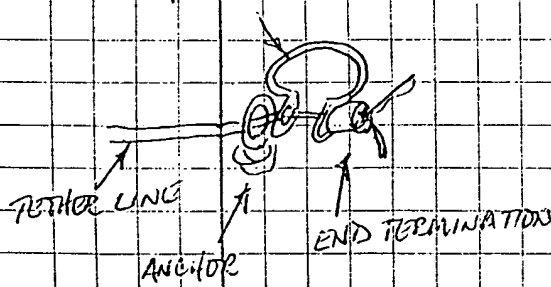
*Handwritten signature* 2/24/00

## TORSION SPRING IN SERIES WITH TETHERLINE

THE COMPRESSION SPRINGS USED IN SERIES WITH THE TETHER LINE TENDED TO CURL AND BUCKLE WITHOUT SUPPORT. WHEN SUPPORT GUIDES AND END CAPS WERE ADDED, THE SPRING ASSEMBLY BECAME BULKY (SEE PAGE 69). SMALLER DIAMETER SPRINGS AND GUIDES PLACED ON THE OUTSIDE OF THE SPRING WILL REDUCE THE SIZE, BUT ANOTHER CONCEPT WOULD BE TO USE A TORSION SPRING. THE TORSION SPRING WILL POTENTIALLY SIT MUCH FLATTER AND HAVE A LOWER FUNCTIONAL PROFILE. THE STRENGTH OF THE SPRING CAN BE VARIED BY THE WIRE DIAMETER, DIAMETER OF THE COILS, OR NUMBER OF COILS (TURNS)



TORSION SPRING



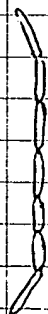
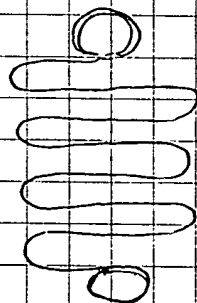
James H. G. 2-9-00

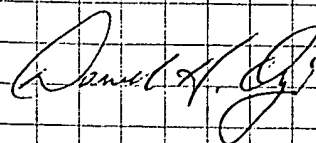
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James H. G. 2/24/00

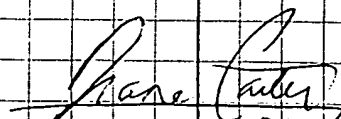
## LOWER PROFILE STAND-OFF

THE "TETHER LINE" GUIDE RINGS ARE CURRENTLY LARGE ENOUGH IN DIAMETER TO SLIDE OVER THE 1.86" SHAFT OF THE ANCHOR DELIVERY SYSTEM. THIS 2.40" DIAMETER HAS THE POTENTIAL TO INTERFERE WITH THE PERICARDIUM, OR CHEST WALL AND COULD ADVERSELY AFFECT THE MOTION OF THE HEART. BY ELIMINATING THE GUIDE RINGS IN THE MIDDLE (BODY) OF THE STAND-OFFS AND TILTING THE END GUIDE RINGS DOWN AT AN ANGLE, IT SHOULD REDUCE THE FINAL PROFILE (HEIGHT) OF THE PART. THE ANGLED, OR FLAT END RINGS CAN BE TILTED UP TO SLIDE OVER THE SHAFT OF THE ANCHOR DELIVERY SYSTEM, TO BE PUSHED OFF ONE AT A TIME.



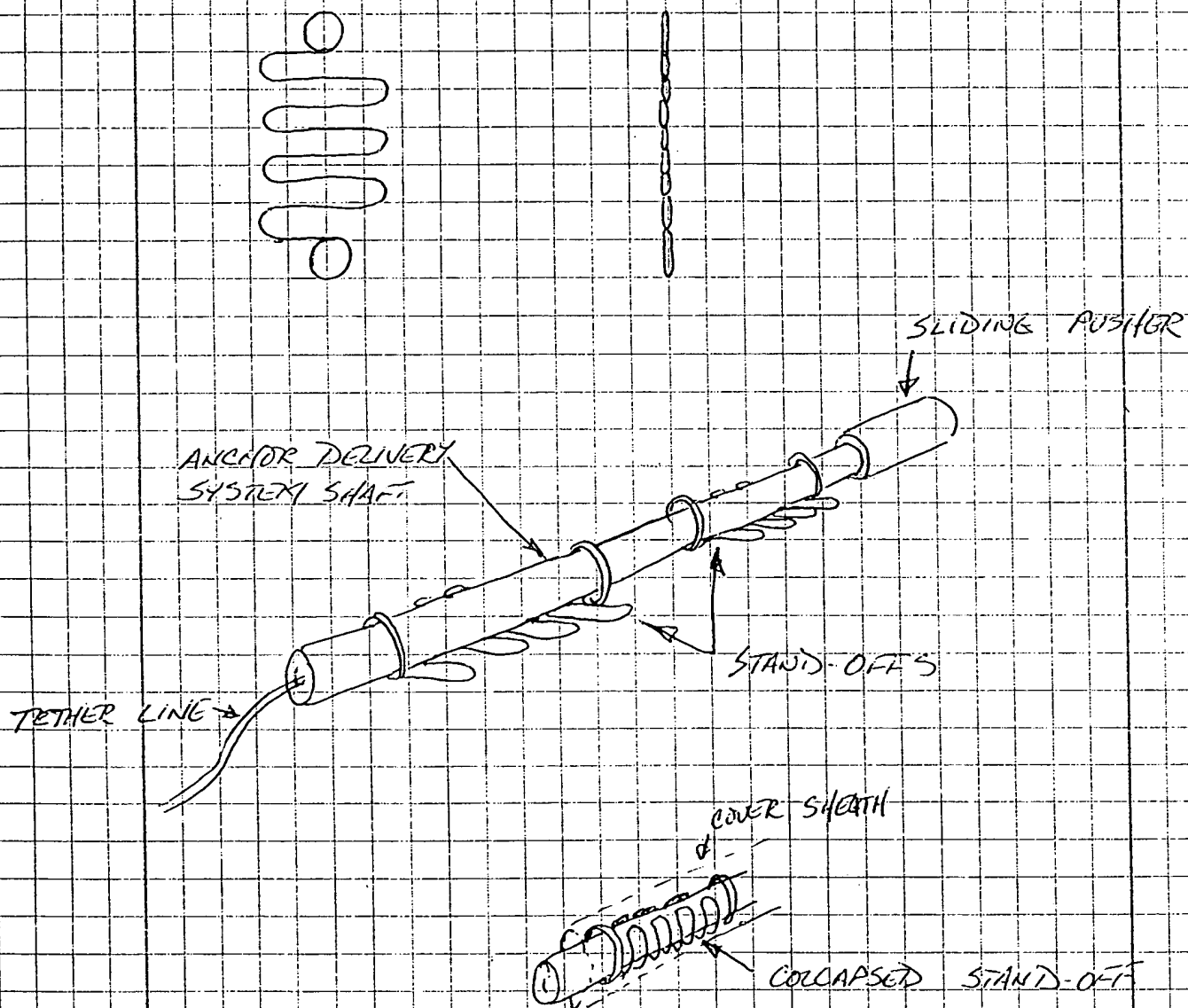
 2-10-00

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 2/10/00

## LOWER PROFILE STANDOFF - CONTINUED

THE END RINGS MAY ALSO BE FORMED  
FLAT INSTEAD OF ANGLED.

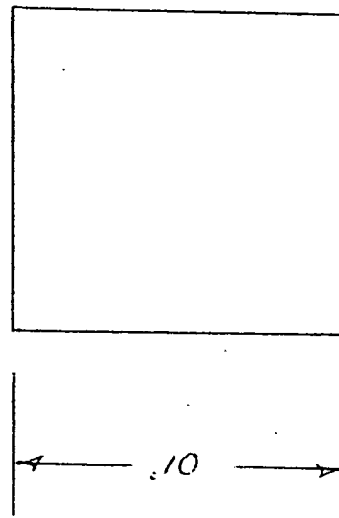
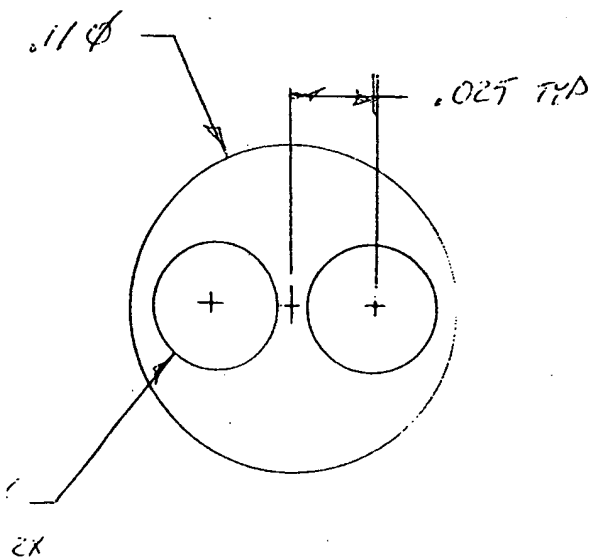


David G. 2-10-00

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None Later 2/21/00

## TETHERLINE END TERMINATION BUTTON



## TWO HOLE TERMINATION BUTTON

MATERIAL: BRASS

TOLERANCES: XX  $\pm .01$   
XXX  $\pm .003$ 

Daniel G. 2-9-00

TWO HOLE TERMINATION BUTTON ALLOWS TETHER LINE  
TO BE THREADED THROUGH THE TWO HOLES, THEN  
SECURED WITH SQUARE KNOTS.

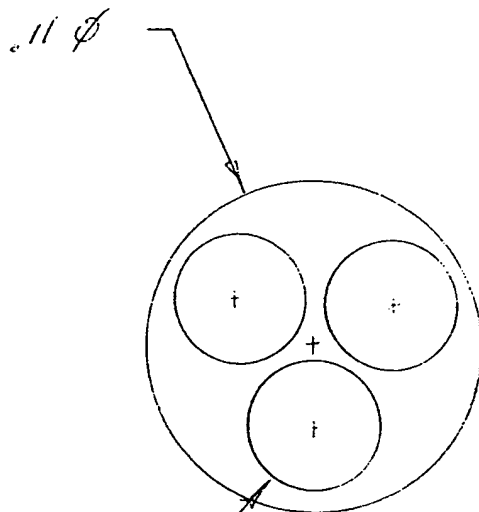
Daniel G.

2-10-00

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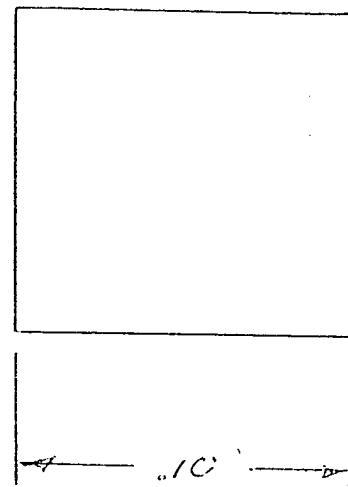
2/24/00

## THREE HOLE TERMINATION BUTTON



0.04 Ø  
THRU, 3X

HOLE PATTERN, .027 CENTERS,  
120° APART



THREE HOLE TERMINATION BUTTON

MATERIAL: BRASS

TOLERANCES: XX = ± .01  
XXX = ± .003

(Daniel J. G.) 2-9-00

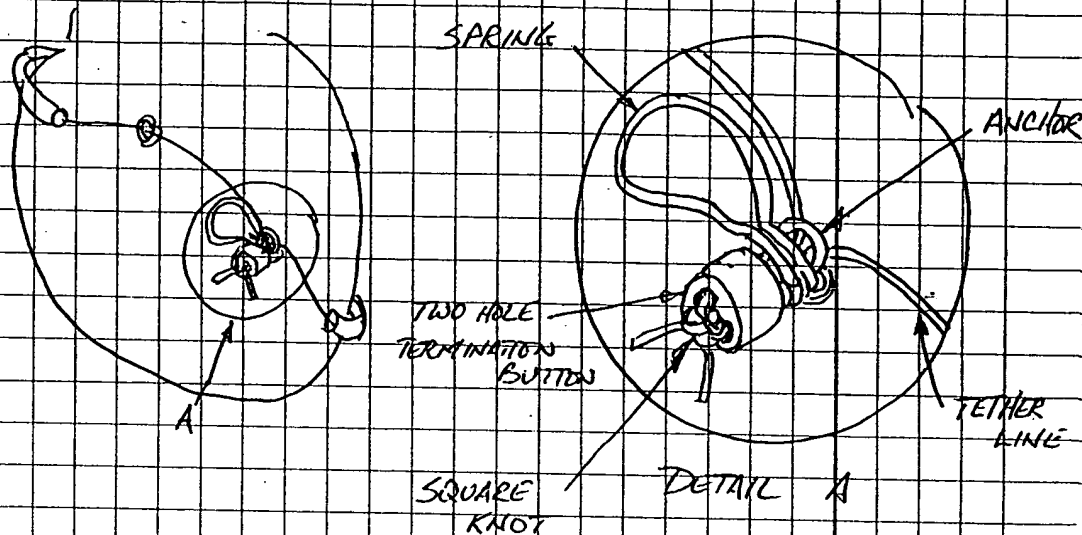
A THREE HOLE TERMINATION BUTTON MAY BE USED  
TO KEEP THE TETHER LINE COMPRESSION SPRINGS,  
OR TETHER LINE TORSION SPRING IN LINE  
WITH THE HARNESS WHEN USING THE RIGID  
SUPPORT TUBE, RATHER THAN AT 90°.

(Daniel J. G.) 2-10-00

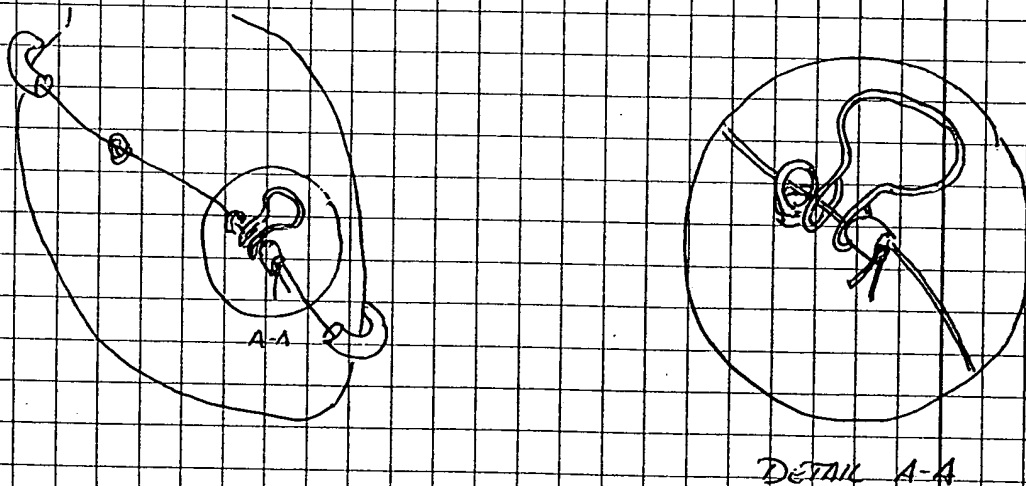
READ +  
UNDERSTAND

D. J. G. 2/24/00

## THREE HOLE TERMINATION BUTTON CONTINUED



## TWO HOLE TERMINATION BUTTON



## THREE HOLE TERMINATION BUTTON

THE TWO HOLE BUTTON COULD ALSO BE USED IN-LINE IF A DOUBLE TETHER LINE IS USED AND STARTED AT THE SAME ANCHOR AS IT TERMINATES, OR AT THE END OF THE RIGID TUBE SUPPORT.

David V. G. 2-10-00

RED  
STUDY  
2/21/07

## TORSION SPRINGS IN SERIES WITH TETHER LINE

Torsion springs for partial harness assist.

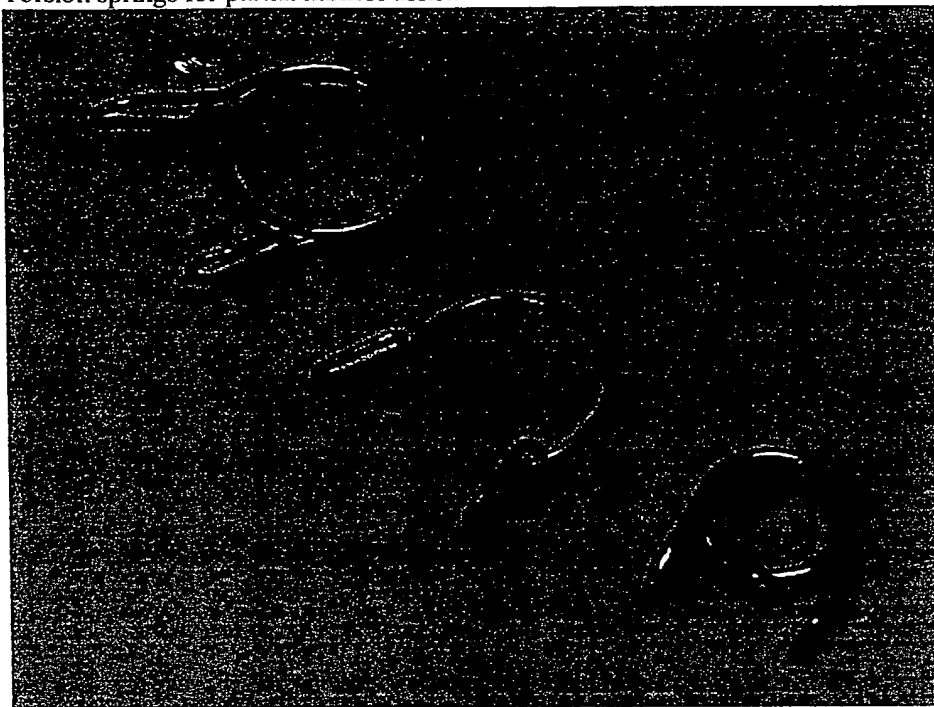


Figure 1: Spring forces vary with wire diameter and number of turns. Above springs have 0.5lb, 1.5-2.0lb and 4.5lb from left to right (.026" and .036" wire).

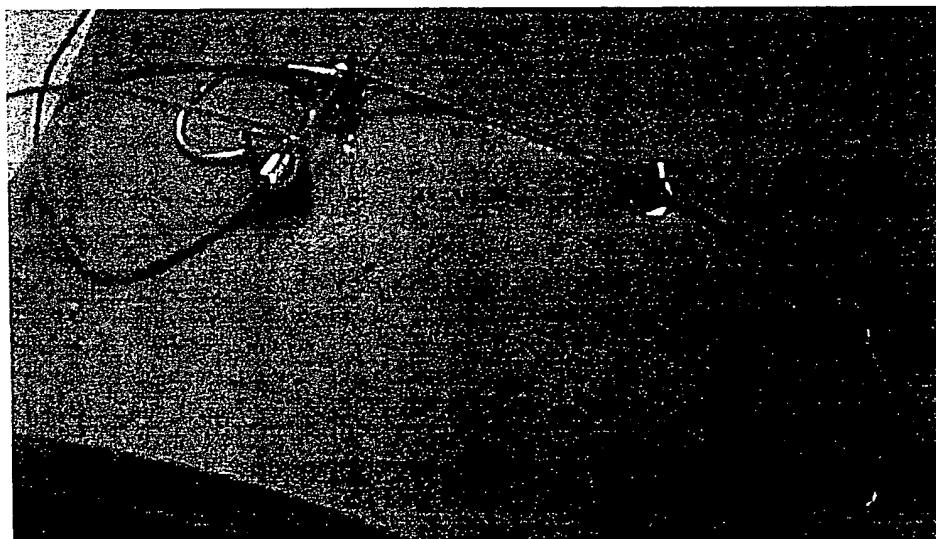


Figure 2: Tether line routed through anchors and rigid support tube, then terminated with a torsion spring and two line termination button.

Wendell H. Clegg 4/13/00

ROD  
&  
UNDERSTOOD

Paul C. Miller 9/24/00



## TORSION SPRINGS IN SERIES CONTINUED.

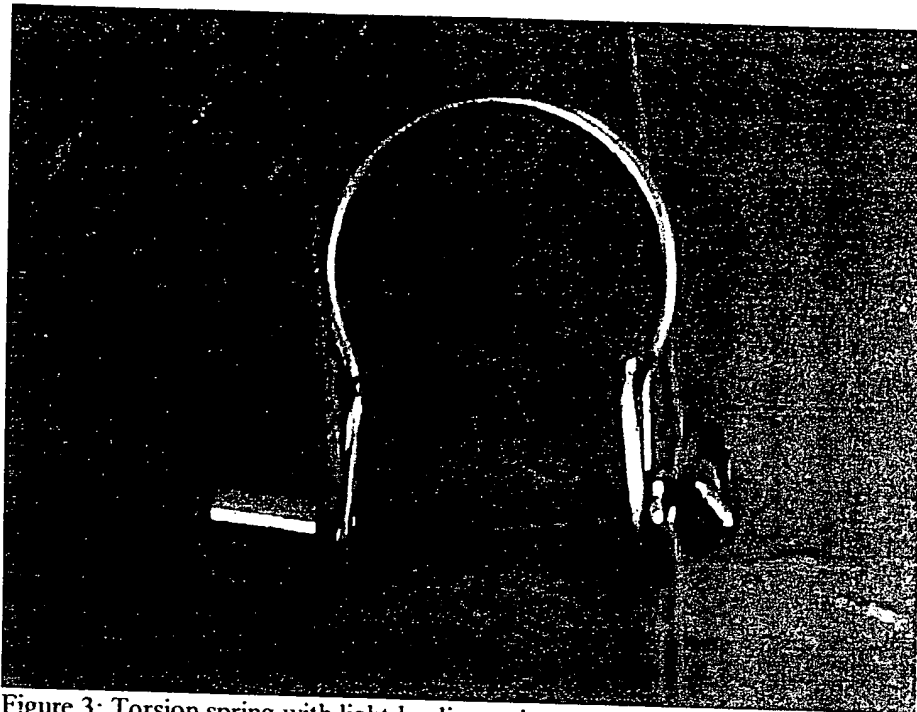


Figure 3: Torsion spring with light loading, prior to slack in the tether line.

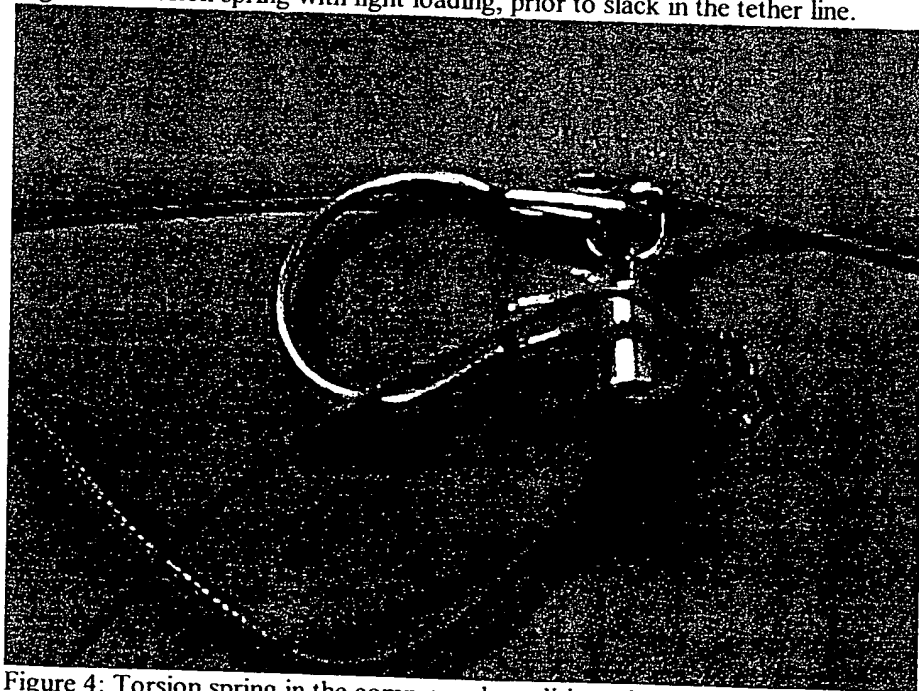


Figure 4: Torsion spring in the compressed condition, almost fully loaded.

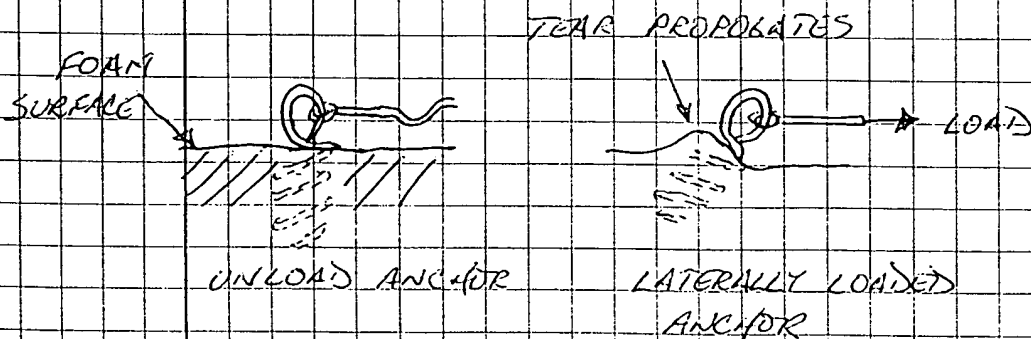
Revised 2/10/00

READ  
UNDERSTOOD

Revised 2/24/00

## ANGLED END ANCHORS

TO REDUCE THE LATERAL STRESSES INDUCED ON THE MYOCARDIUM BY THE LATERAL LOADING OF THE PASSIVE HARNESS ANCHORS (ESPECIALLY THE END ANCHORS), THE COIL ANCHORS MAY BE DRIVEN INTO THE TISSUE AT AN ANGLE, TO COUNTER ACT THE LATERAL LOAD. IT HAS BEEN NOTED WHEN LATERAL LOAD IS APPLIED TO A COILED ANCHOR DRIVEN STRAIGHT INTO (PERPENDICULAR TO THE SURFACE) IN A FOAM MODEL, THE SURFACE OF THE FOAM WILL EVENTUALLY TEAR AND BECOME COMPROMISED. BY PLACING THE ANCHORS AT A  $45^\circ$  ANGLE, OR GREATER, THE LATERAL LOAD AT THE SURFACE, MAY BE REDUCED.



*David W. [Signature]*

2-12-00

READ

UNDERSTOOD

*David [Signature]* 3/2/00

# ANGLED ANCHOR CONTINUED

CENTERLINE OF  
ANCHOR

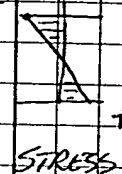
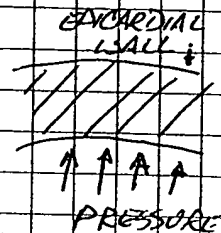
45°

UNLOADED  
ANGLED ANCHOR

REDUCED SURFACE STRESS

LATERAL LOAD

LESS MOMENT SHOULD BE CREATED AT THE SURFACE, SINCE THE ANCHOR DOES NOT HAVE TO TILT AS MUCH FROM THE NEUTRAL PERPENDICULAR ORIENTATION. THIS MAY BE SIGNIFICANT, SINCE THE SURFACE STRESSES ON THE EPICARDIAL WALL OF THE LEFT VENTRICLE HAVE THE HIGHEST TENSILE STRESSES WHEN PRESSURIZED.



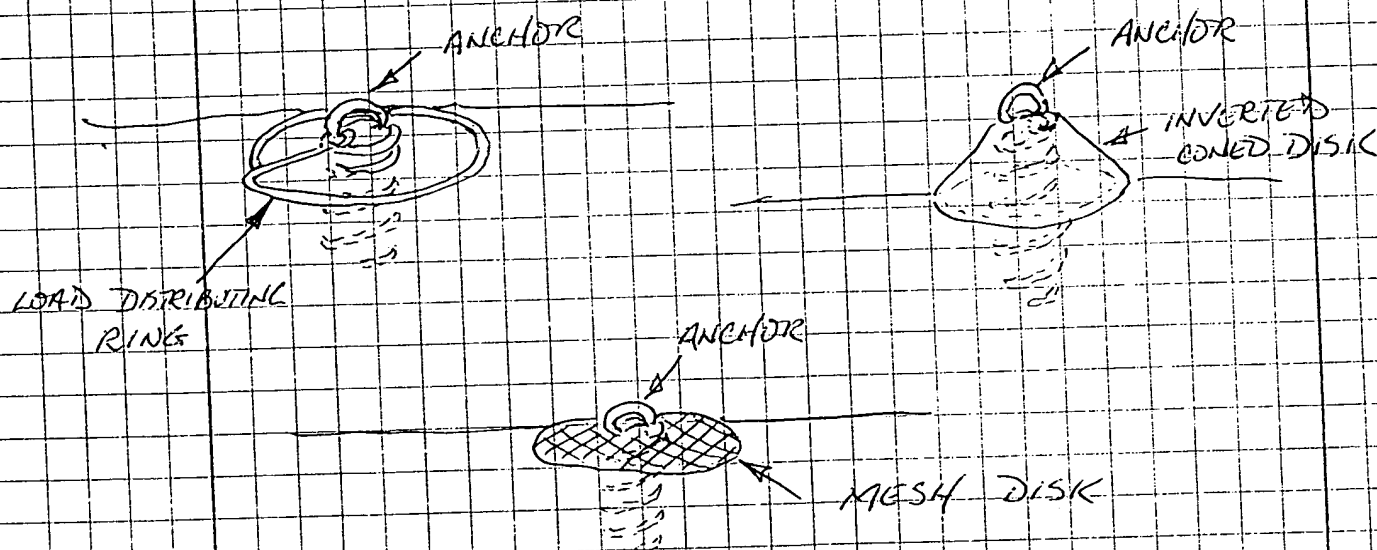
David H. G. 2/12/00

READ +  
UNDERSTOOD

Gene Carter 2/11/00

# STRAIN RELIEF CAP FOR ANCHORS

ANOTHER METHOD TO REDUCE STRAIN AT THE EPICARDIAL SURFACE IS TO INCREASE THE CONTACT SURFACE OF THE ANCHOR. THIS INCREASED SURFACE AREA CAN BE ACCOMPLISHED BY A WIRE LOOP WITH A SIGNIFICANTLY LARGER DIAMETER THAN THE ANCHOR, A SEPARATE CONICAL, OR CONVEX DISK, OR A MESH SURFACE TO ALLOW FIBROSIS TO OCCUR THROUGHOUT THE MESH FOR LONG TERM STABILITY AND SECURITY.



THE THEORY OF THESE DISKS, OR RINGS IS TO STABILIZE AND SUPPORT THE EPICARDIAL SURFACE AND REDUCE STRAIN WITH LATERAL LOADING TO THE ANCHORS.

David A. [Signature]

2-14-00

READ  
&  
UNDERSTOOD

David Carter 2/24/00

## MODIFIED PEACE MAKER

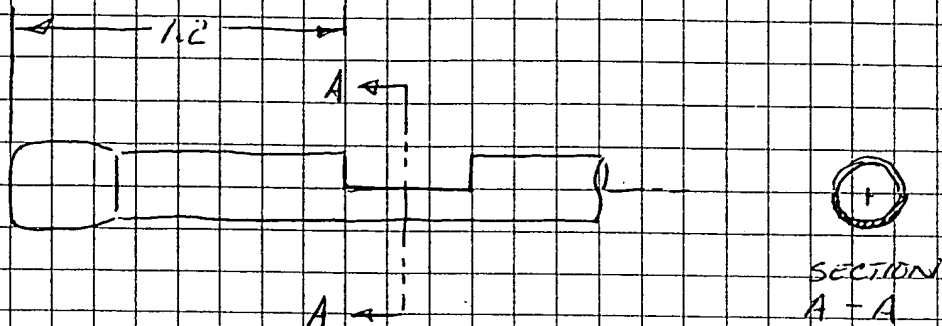
THE MULTI-ANCHOR DELIVERY SYSTEM MAY BE MODIFIED TO FUNCTION AS A SINGLE SHOT DELIVERY SYSTEM THAT WILL NOT REQUIRE THE FULL RETRACTION AND SEPARATION OF THE DRIVE ROD FROM THE HOUSING/BODY OF THE DELIVERY MECHANISM. A SLOT LONG AND WIDE ENOUGH TO ACCOMMODATE AN ANCHOR CAN BE MACHINED, OR GROOVED INTO THE DELIVERY TUBE, PROXIMAL OF THE THREADED TIP OF THE DELIVERY TUBE. TO REDUCE DELIVERED PROFILE OF THE CARDIAC HARNESS, THE LOOP OF THE ANCHOR MAY BE SHORTENED IN HEIGHT TO WHERE THE TETHER LINE LOOP WILL ONLY BE AS TALL (THE GAP) AS THE TETHER LINE IS THICK. TO DRIVE THE LOWER PROFILE ANCHOR, THE DRIVE MECHANISM MAY HAVE TO BE MODIFIED, BY HAVING PROTRUDING PINS RATHER THAN A SLOT MACHINED INTO THE END OF THE DRIVE ROD.

James (G) 2/16/00

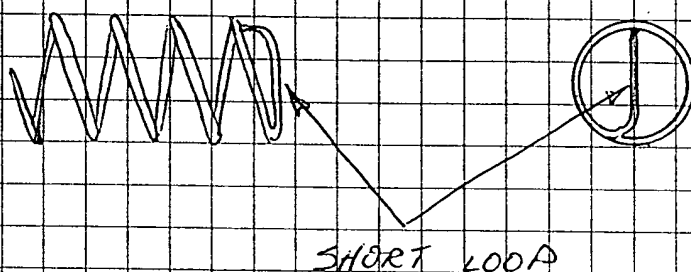
RETD  
UNDERSTOOD

James (G) 2/21/00

## MODIFIED PEACEMAKER - CONTINUED

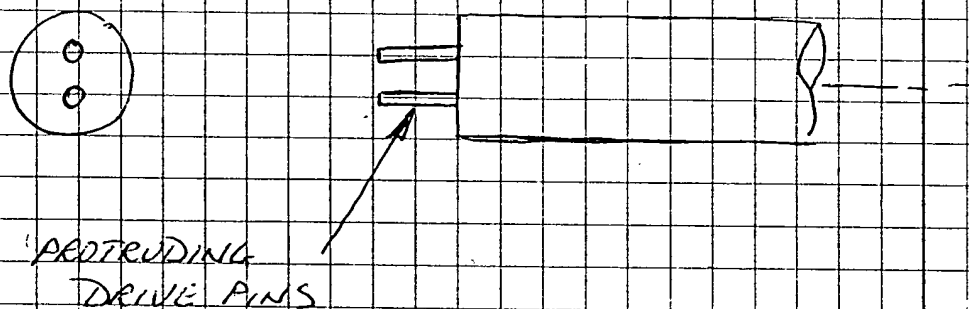


SLOT IN DELIVERY TUBE



SHORT LOOP

MODIFIED LOW PROFILE ANCHOR

PROTRUDING  
DRIVE PINS

MODIFIED ANCHOR DELIVERY DRIVE MECHANISM

David H. G.

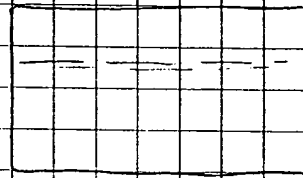
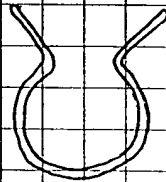
2-16-00

READ  
+  
UNDERSTOOD

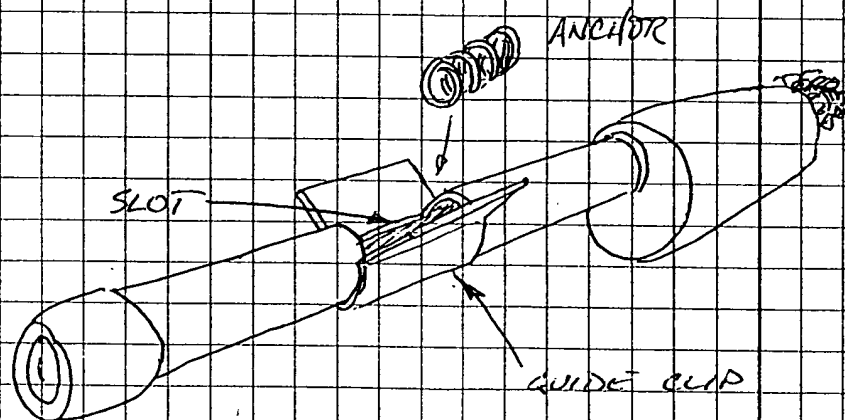
2/24/00  
David H. G.

## MODIFIED PEACEMAKER CONTINUED

TO HELP CENTER AND GUIDE THE MODIFIED ANCHORS INTO THE SIDE SLOT OF THE DELIVERY TUBE, A SHEET METAL GUIDE, OR CLIP CAN BE MADE TO SLIDE OVER THE DELIVERY TUBE. THE CLIP CAN BE FLARED AT THE OPEN END TO HELP "FUNNEL" THE ANCHORS INTO THE SLOT.



GUIDE CLIP



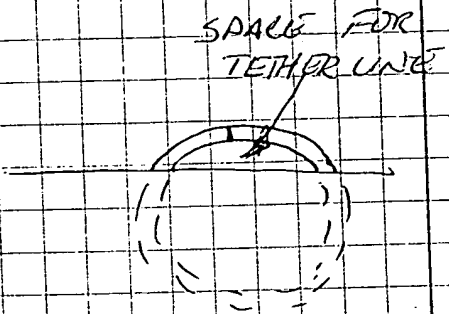
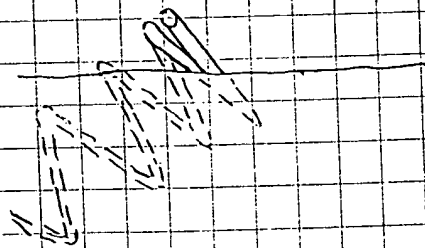
*Handwritten signature*

2-16-00 READ  
UNDERSTOOD

*Handwritten signature* 2/24/00

## ANGLED END ANCHORS

A METHOD FOR INSERTING THE ANCHORS AT AN ANGLE WOULD BE TO SET THE DELIVERY DEVICE NORMAL TO THE EPICARDIAL SURFACE FOR ONE TO TWO REVOLUTIONS OF THE ANCHOR/DRIVE MECHANISM, THEN TILT THE DELIVERY DEVICE AT A <sup>DRIVE</sup> ~~30-45~~ <sup>2-16-00</sup> 45° ANGLE AND COMPLETE THE INSERTION AT AN ANGLE. THIS METHOD SHOULD ALLOW THE ANCHOR TO START INTO THE TISSUE, BUT THEN BE DRIVEN FURTHER INTO THE TISSUE AT AN ANGLE. ANGLED SINGLE SHOT (CLOSED LOOP) ANCHORS MAY LEAVE MORE OF A TETHER LINE LOOP EXPOSED WHEN INSERTED AT AN ANGLE.



Samuel X. G.

2-16-00

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+ UNDERSTOOD

Done 2/24/00



## ALTERNATE ANCHOR TERMINATION

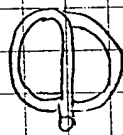
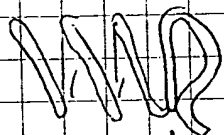
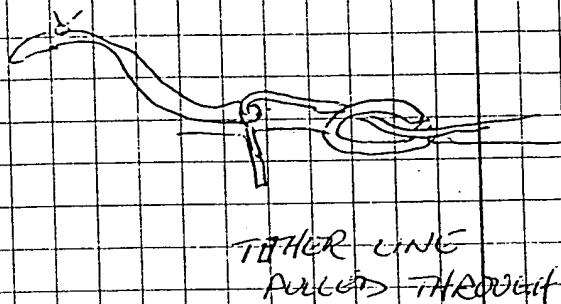
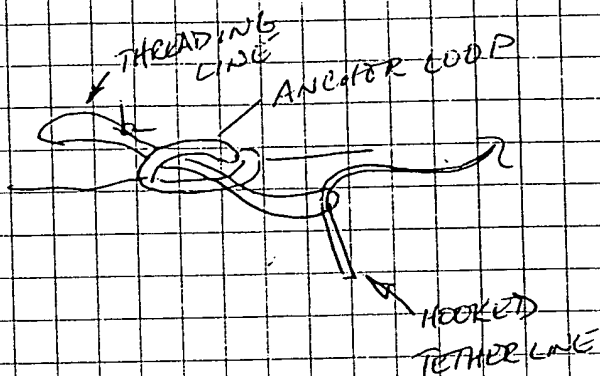
IF THE ANCHORS ARE INSERTED INTO THE MYOCARDIUM PRIOR TO THE TETHER LINE BEING ATTACHED, THEY CAN BE THEADED AFTER INSERTION, OR THE ANCHOR TERMINATION MAY ALLOW "QUICK", ONE WAY CAPTURE OF THE TETHER LINE. WITH A (CLOSED) LOOP, A LARGE LOOPED "THRUSTER" LINE MAY BE LEFT IN THE ANCHOR LOOP AFTER INSERTION AND USED TO PULL THROUGH THE TETHER LINE. WITH AN OPEN LOOP, THERE MAY BE A SPRING FIT, OR TORTUOUS PATH TO ALLOW THE TETHER LINE TO SLIP IN, BUT NOT SLIP OUT. A DEFORMABLE SECONDARY PIECE MAY BE ATTACHED TO THE ANCHOR COIL TO ALLOW A TYPE OF SNAP FIT TO CAPTURE THE TETHER LINE. THIS FEATURE MAY BE PHOTO ETCHED, OR LASER CUT FROM SHEET METAL TO VARY THE THICKNESS OF SPECIFIC SECTIONS TO ENHANCE THE SNAP FIT FEATURES.

*[Signature]* 2-16-00

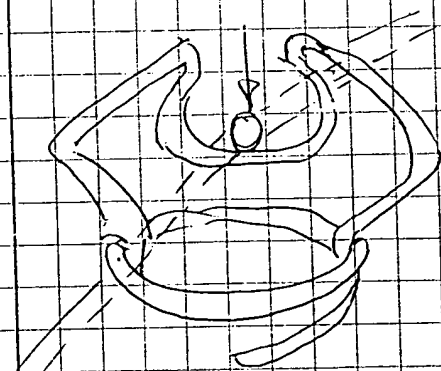
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UNDERSTOOD

*[Signature]* 2/24/00

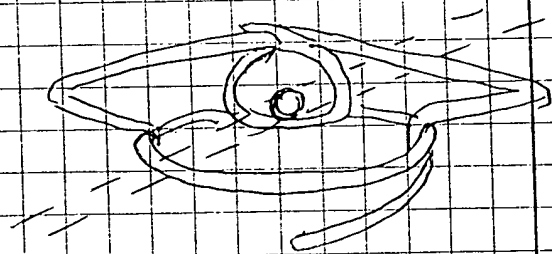
## ALTERNATE ANCHOR TERMINATION CONTINUED



TETHER LINE TO PULL THROUGH

TETHER LINE  
PUSHES DOWN

OPEN POSITION



CLOSED POSITION

David R. G.

2-16-00

READ

\* UNDERSTOOD

David R. G. 2/17/00

LOW PROFILE ANCHORS, STANDOFF AND SPRING

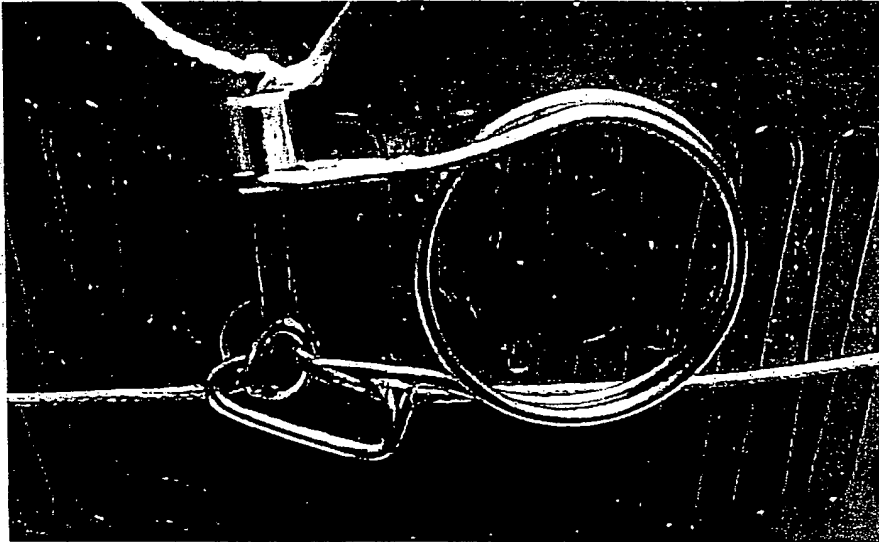


Figure 1: Torsion termination spring with single tether line and termination button.

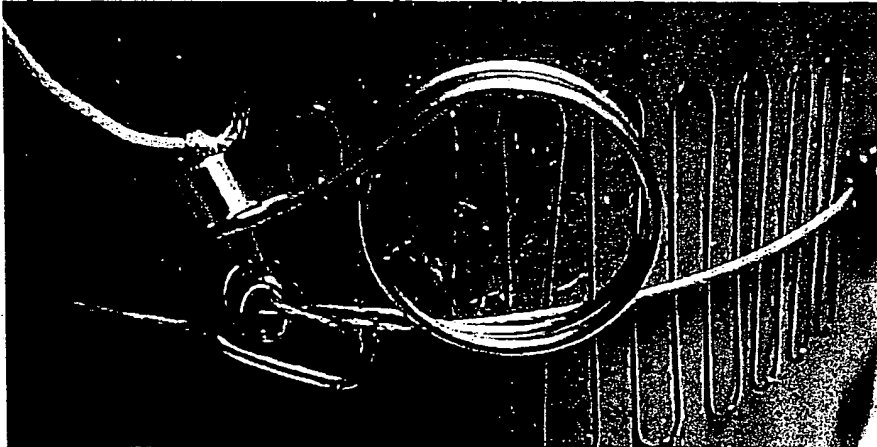


Figure 2: Torsion spring in higher tension.

THE LOWER PROFILE ANCHORS, STANDOFFS AND  
TORSION SPRINGS SIGNIFICANTLY REDUCE THE  
HEIGHT OF THE PASSIVE, SPRING ASSISTED  
HARNESSES

David A. G.

2/23/00

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UNDERSTOOD

3/24/00

## LOW PROFILE HARNESS - CONF

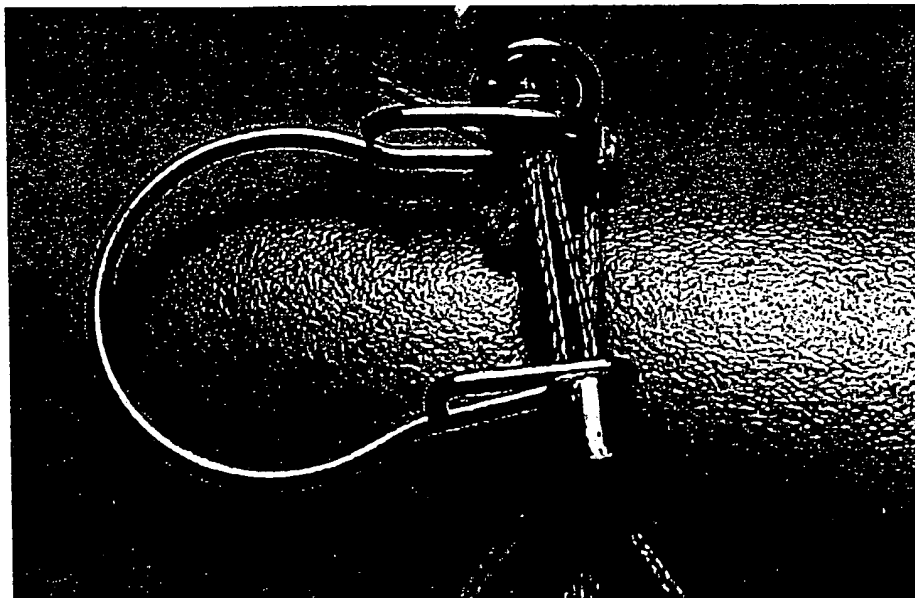


Figure 3: Torsion spring with dual tether line and anchor point on back bar.

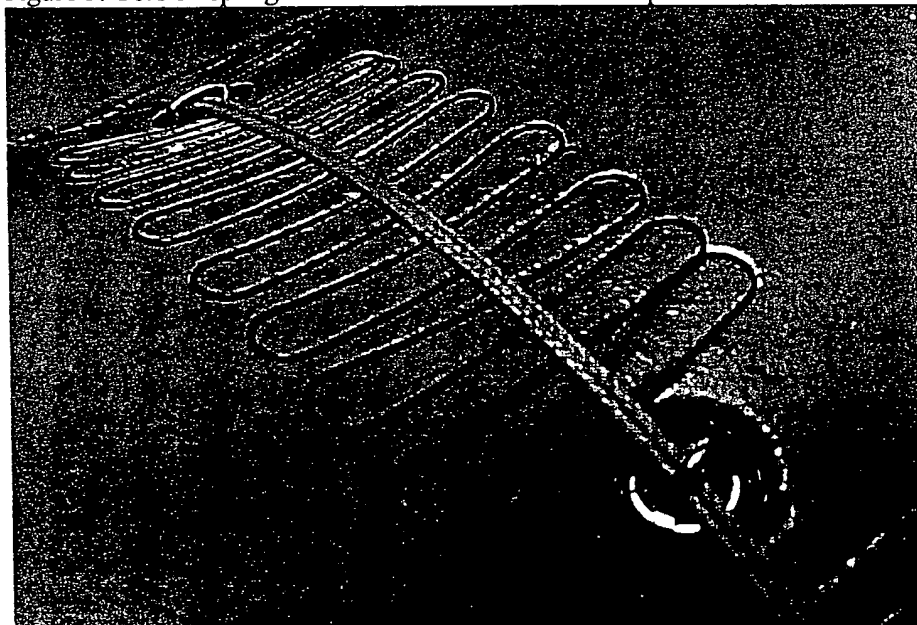


Figure 4: Low profile anchors and stand-offs interfere less with the pericardium.

ANCHOR POINT SOLDERED TO THE BACK BAR  
 ALLOWS FOR DUAL TETHER LINE.

Don't / G 2/23/00

READ  
 & UNDERSTOOD

3/2/00

LOW PROFILE HARNESS CONT.

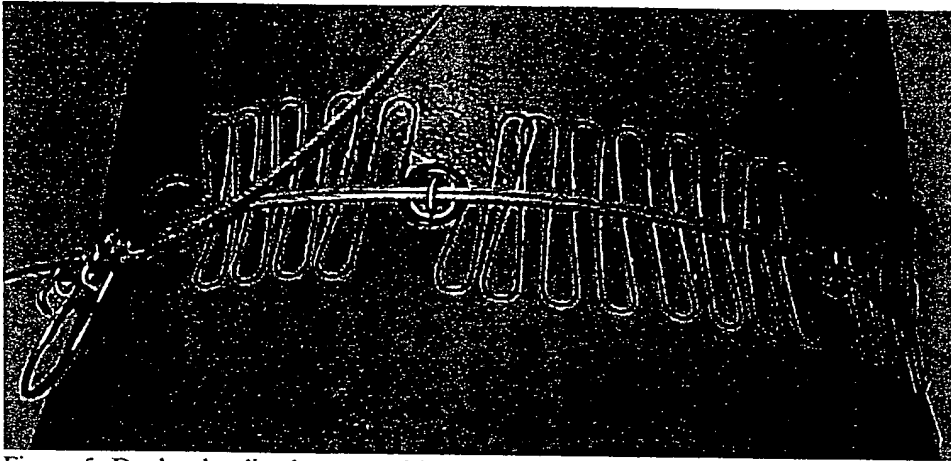


Figure 5: Dual tether line harness with low profile anchors, spring and stand-offs.

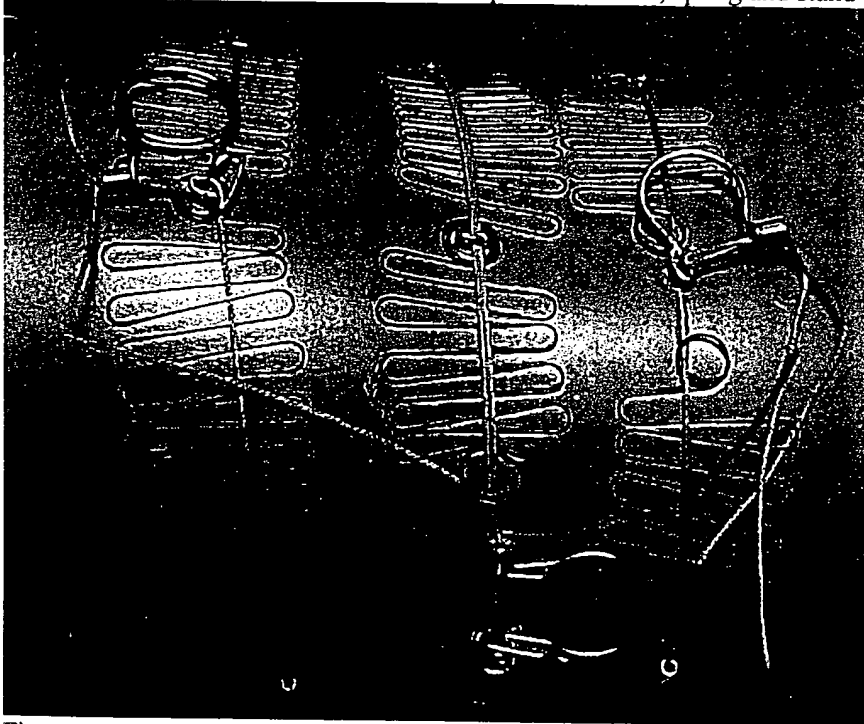


Figure 6: Three different configurations of tether lines, torsions springs, back bars and stand-offs.

END STAND-OFF LOOPS FIT OVER ANCHORS TO  
KEEP THEIR POSITION.

David G. 2/25/00

REDA.

UNDESIGNED

John Long 3/25/00

## MODIFIED ANCHOR DELIVERY SYSTEM (LOW PROFILE)

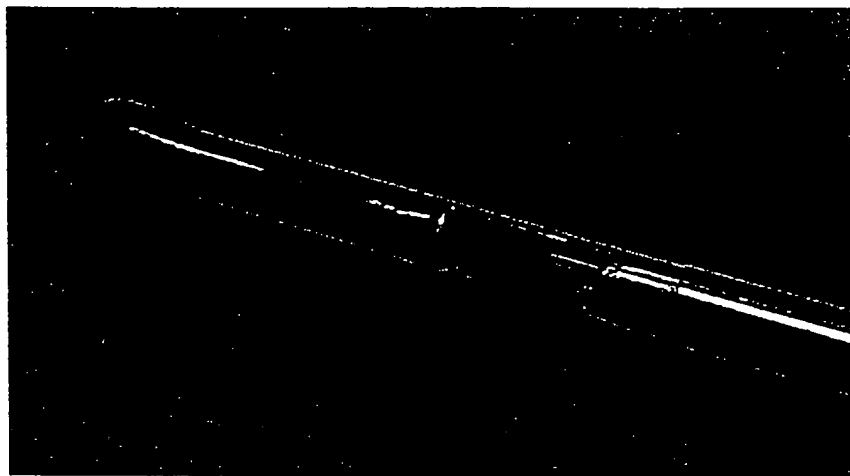


Figure 1: Slot for anchor insertion and pins for low profile anchor drive.

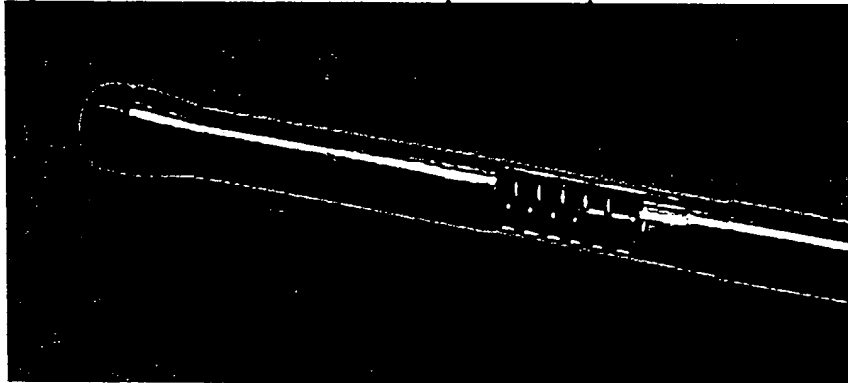


Figure 2: Low profile anchor engaged by drive pins.

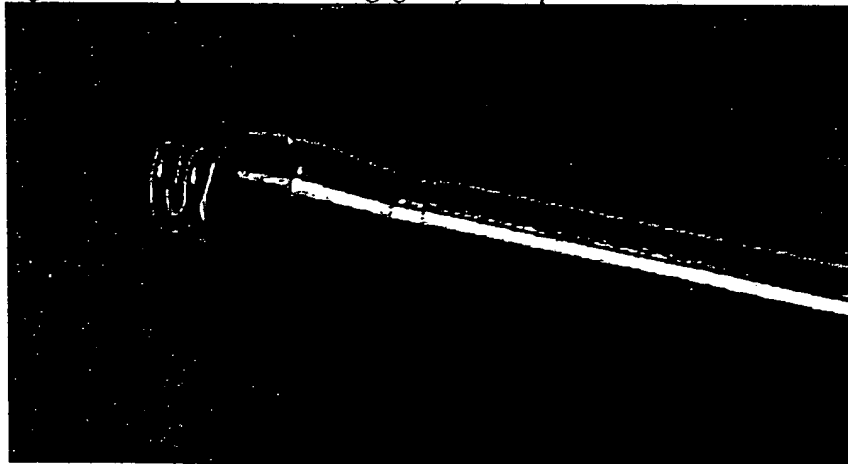


Figure 3: Low profile anchor being driven from delivery device. Note, sleeve is covering the slot.

David H. G. 2/23/00

Revis  
understood

3/24/00

# LOW PROFILE ANCHORS AND DELIVERY CATH



Figure 4: Low profile anchor being driven into foam model.

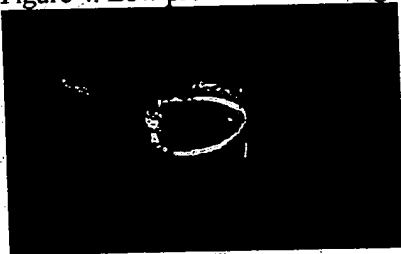


Figure 5: Low profile anchor in foam model.

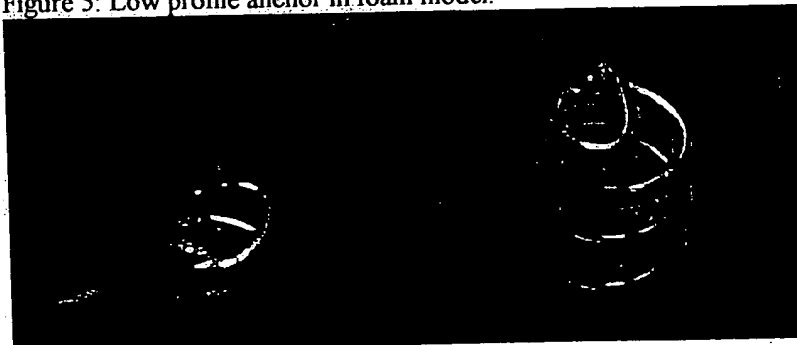


Figure 6: Low profile anchors fully inserted and partially inserted.

SOLDERED END LOW PROFILE ANCHOR IS MADE  
OF 302 STAINLESS STEEL WITH A NICKEL COATING.  
ANCHORS MAY BE ELECTRO POLISHED BEFORE CHRONIC  
ANIMAL STUDIES

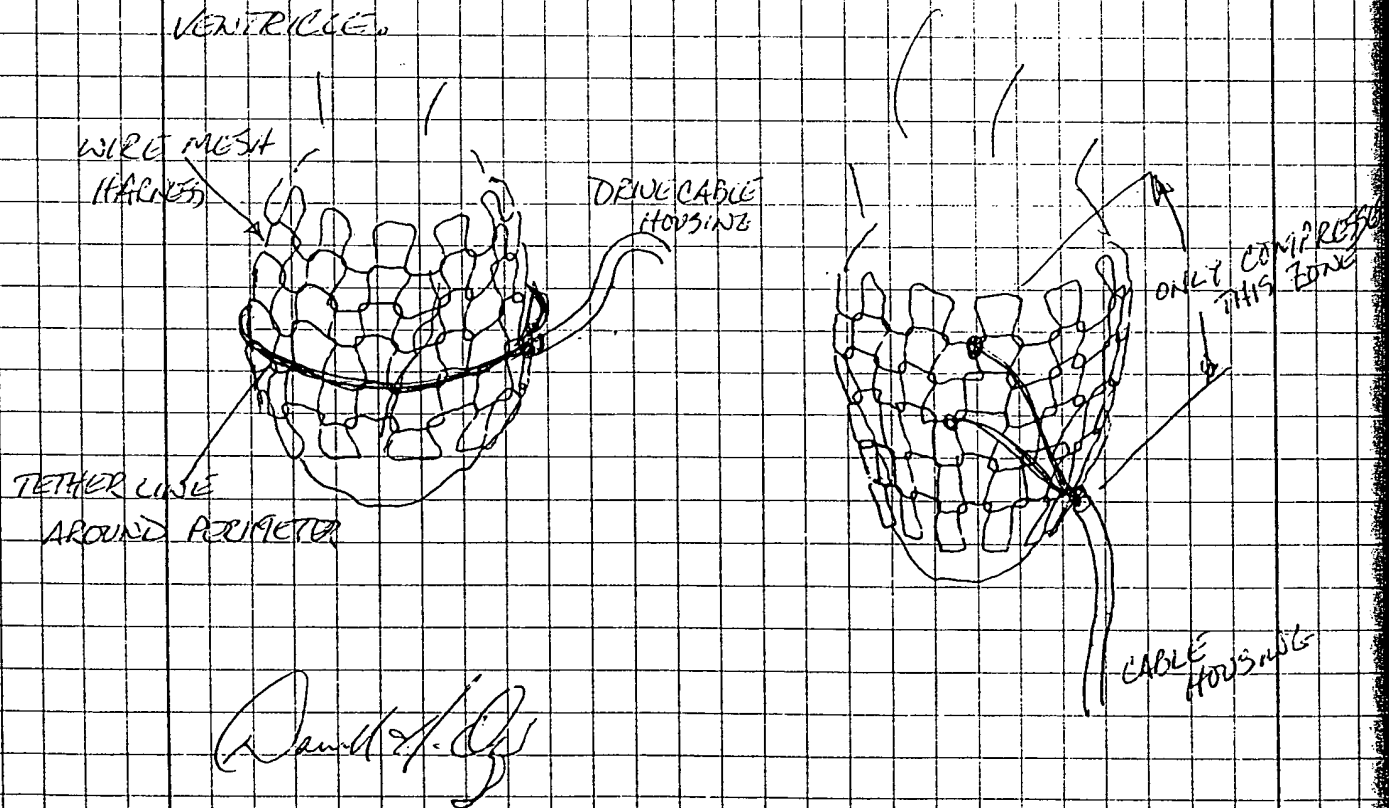
Paul H. Ch 2/23/00

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✓  
UNDERSTOOD

2/27/00

# ACTIVELY DRIVEN WIRE MESH HARNESS

THE WIRE MESH HARNESS MAY BE COMPRESSED BY ADDING A TETHER LINE, OR CABLE AROUND THE CIRCUMFERENCE OF THE HARNESS, OR MAY BE ATTACHED TO A PORTION OF THE HARNESS TO PARTIALLY COMPRESS THE HARNESS. THIS PARTIAL COMPRESSION WOULD ALLOW TARGETING COMPRESSION TO SECTIONS OF THE HEART SUCH AS THE LEFT VENTRICLE.



*David A. G.*

2-25-00

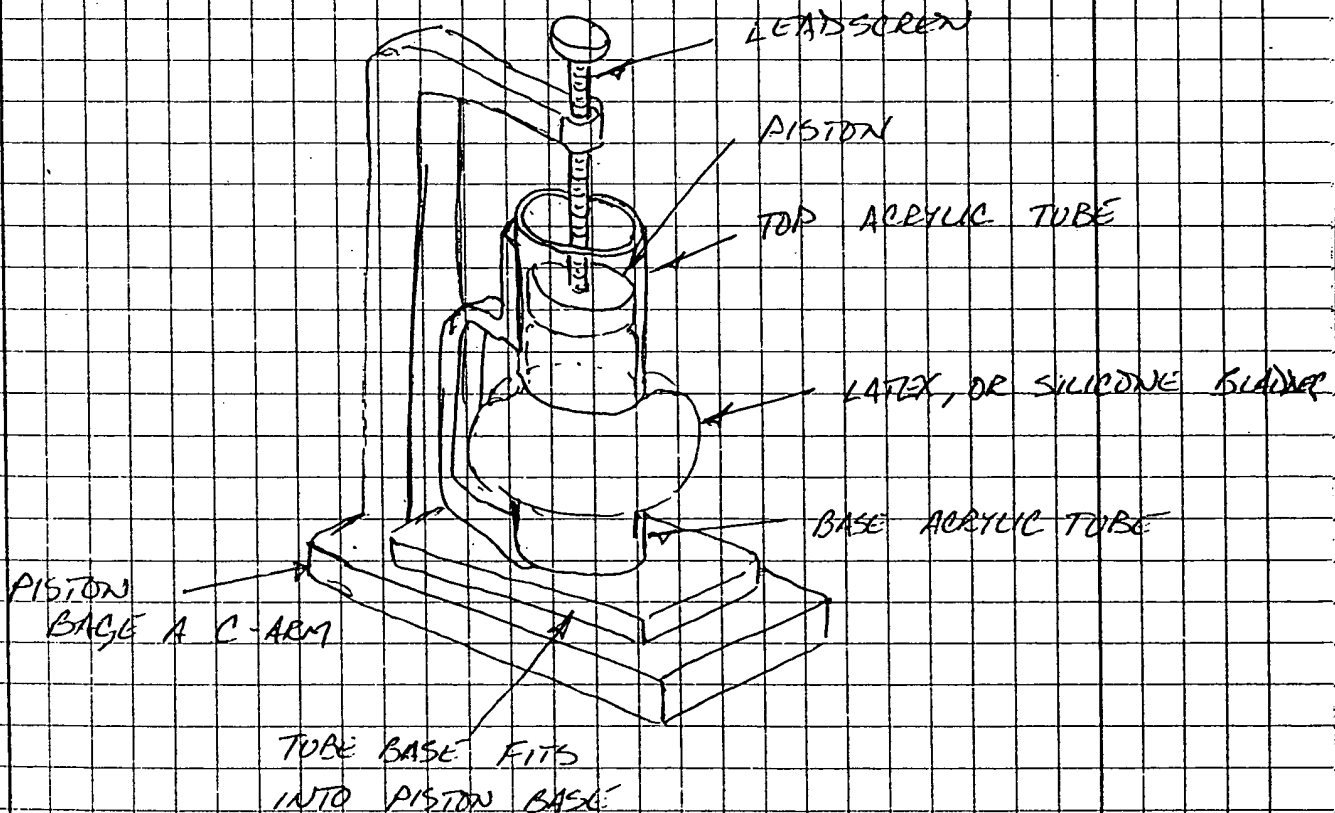
READ + UNDERSTOOD

*David A. G.* 3/29/00



# PRESSURE VS VOLUME TESTER

A TEST FIXTURE WILL BE NEEDED TO EVALUATE THE PRESSURE THE WIRE MESH HARNESS WILL EXERT ON THE HEART IN DIFFERENT CONFIGURATIONS AND DIFFERENT DIAMETERS. THE FIXTURE/TESTER SHOULD BE ABLE TO CHARACTERIZE DIAMETER CHANGE IN A BLADDER (WITH HARNESS) GIVEN A CHANGE IN VOLUME. PRESSURE AT GIVEN DIAMETERS WILL ALSO BE IMPORTANT.



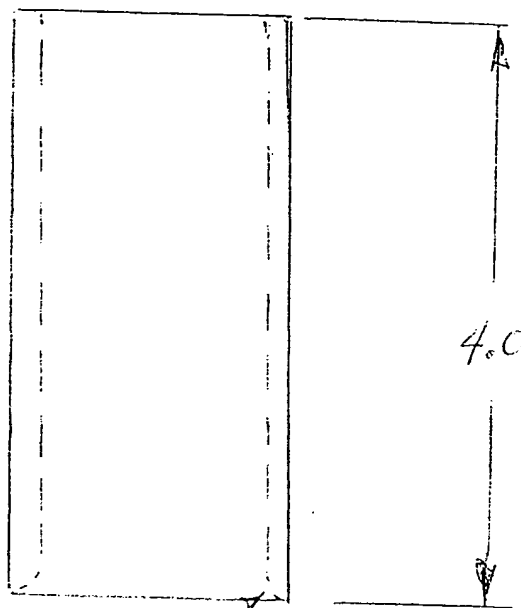
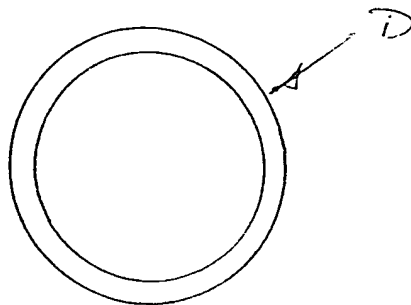
*Handwritten signature*

2-25-00

READ  
+ UNDERSTOOD

*Handwritten signature* 3/29/00

## PV TESTER COMPONENT PARTS



SMOOTH RADIUS (ONE END)

TOP TUBE

MATC: ACRYLIC (SUPPLIER)

TOL:  $\alpha = 0.1$

1 EACH DIAMETER

Handwritten signature: *Randy [unclear]* 2-29-00  
3-10-00

REF

710724PCTAX

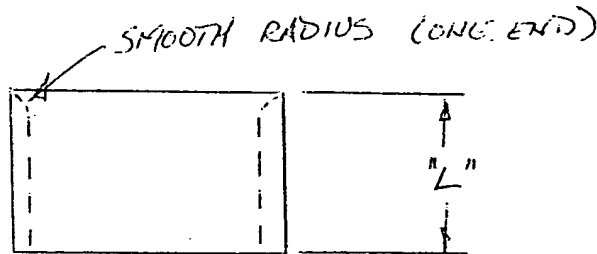
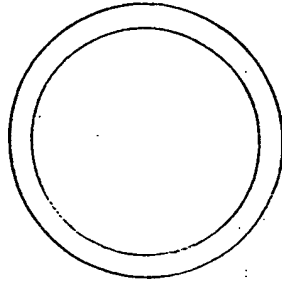
3/29/00

101

# AV TESTER COMPONENT PARTS

1.0

1.5



BASE TUBE

MATERIAL: ACRYLIC (SUPPLIED)

TOL: .X = ± .1

1 EACH DIAMETER

W.H. Co. 2-25-00

3/10/00

READ

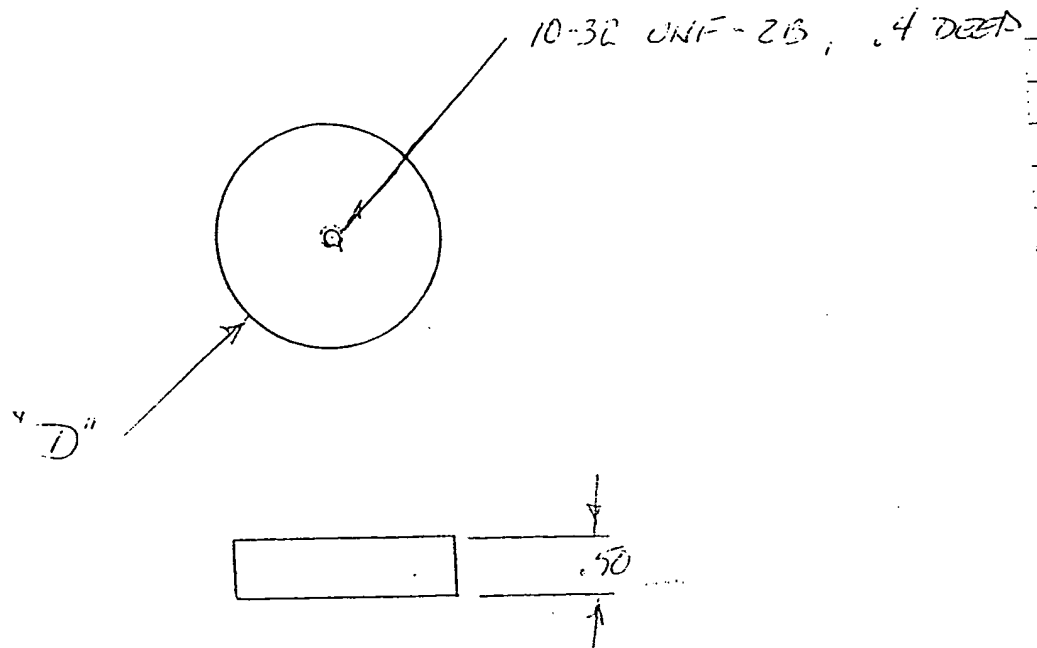
UNDESIGNED

3/24/00

## AV TESTER PARTS

$D_1 = .25"$  LESS THAN ACRYLIC TUBE I.D.

$D_2 = \text{SLIP FIT } (.005-.010) \text{ WITH ACRYLIC TUBE I.D.}$



COMPRESSION PISTON

MATERIAL: ALUMINUM, DELRIN, ACRYLIC OR EQUIV

TOL. = XX =  $\pm .01$

XXX =  $\pm .005$

1 EACH PER ACRYLIC TUBE

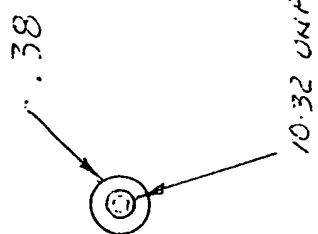
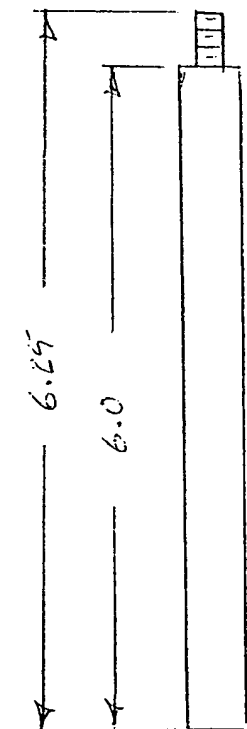
QAC 3/10/00 E-25-00

READ

+ UNDERSTOOD

3/10/01

PV TESTER PARTS



10-32 UNF 2B 0.3 DEEP

THREADED EXTENDER  
MATERIAL: ALUMINUM

TOL: X =  $\pm .01$   
XX =  $\pm .01$

1 EACH

6/1/01 2:25:00

Donald V. G.

3/10/00

READ

3/29/00

PV/AD TESTER

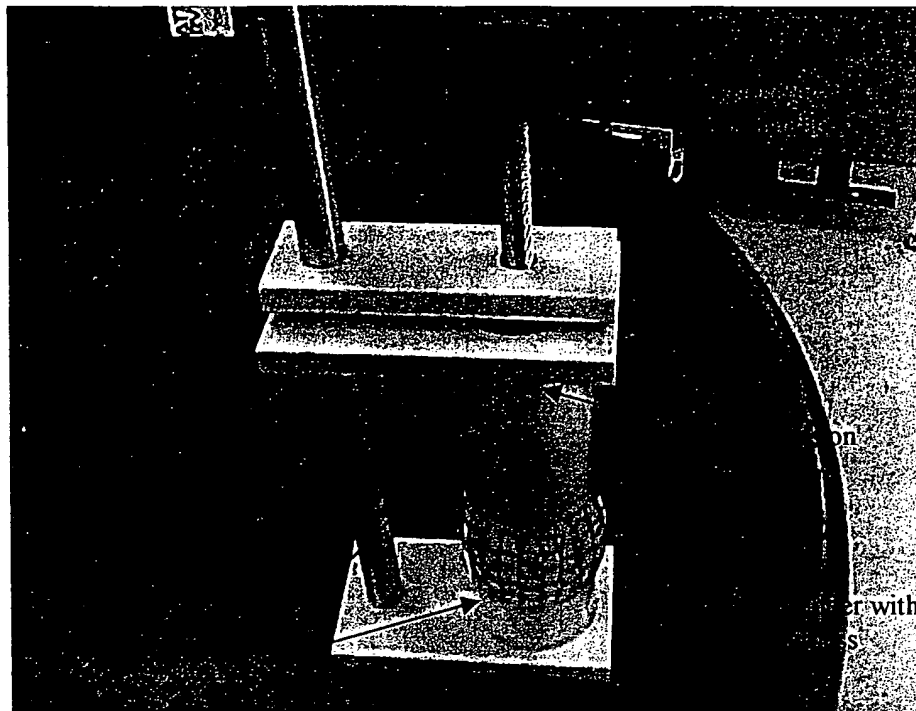


Figure 1: Harness characterization/test fixture.

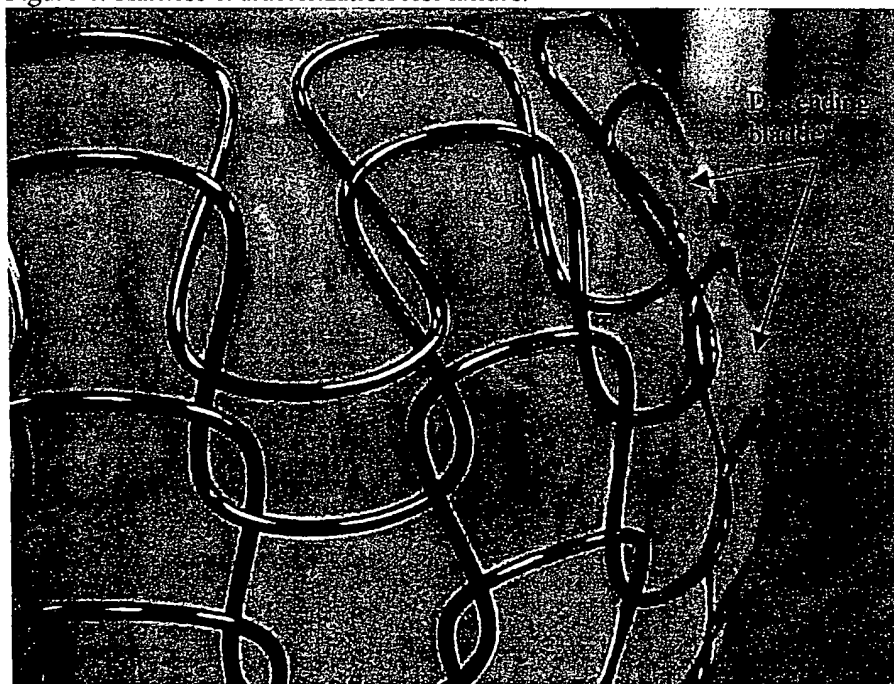


Figure 2: Bladder extruding out between struts at higher pressures (.032").

3/10/00  
R. G. G.

R. G. G.

3/10/00

RGAD

UNDERSTOOD

3/24/00

PV/PD TESTER

5/19/00  
5/19/00

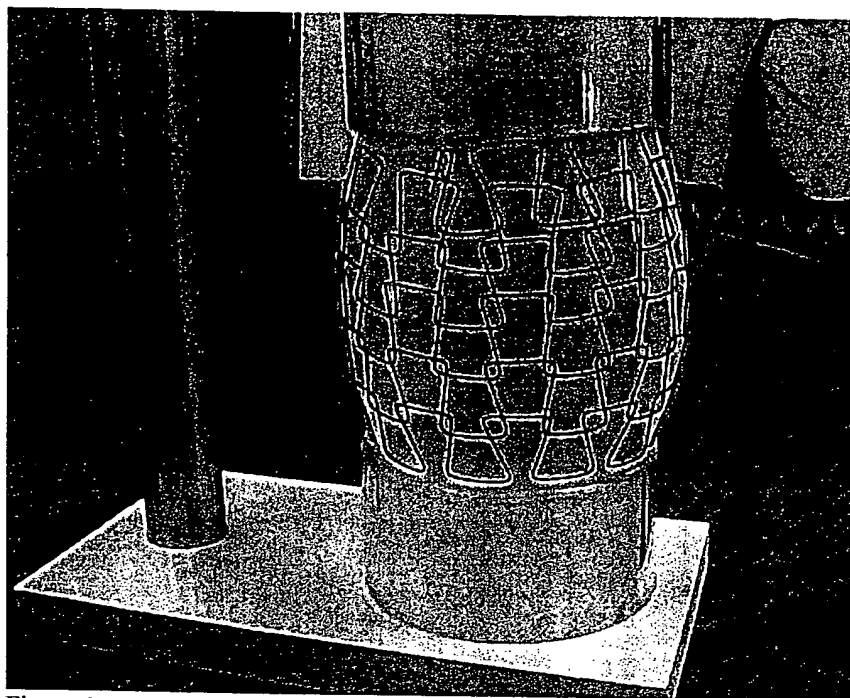


Figure 3: .015" harness slightly pressurized.

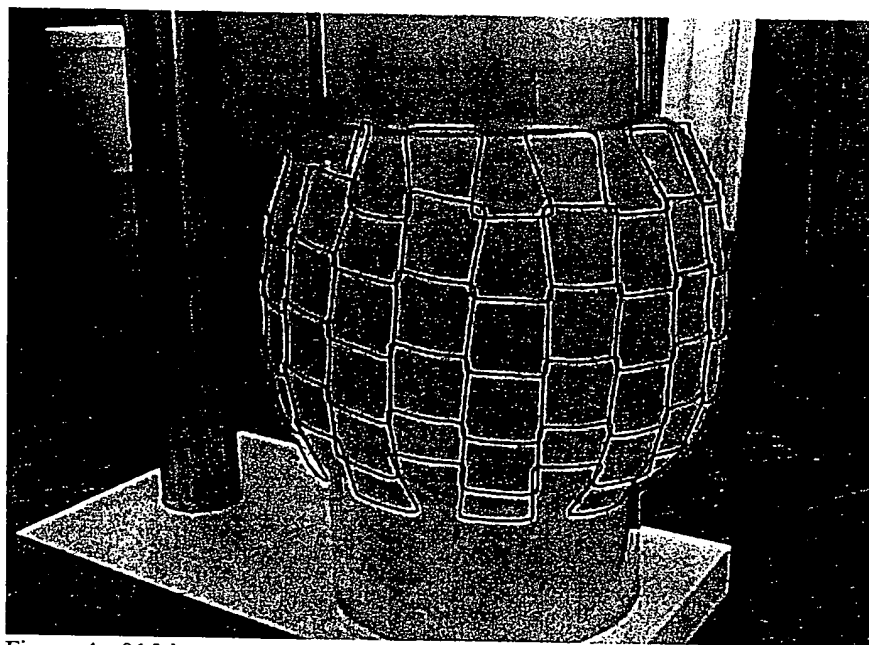


Figure 4: .015 harness extended (note struts at 90°).

*[Handwritten signature]*

3-10-00

RETD

UNDERSTOOD

*[Handwritten signature]*

3/29/00

PV/PD TESTER

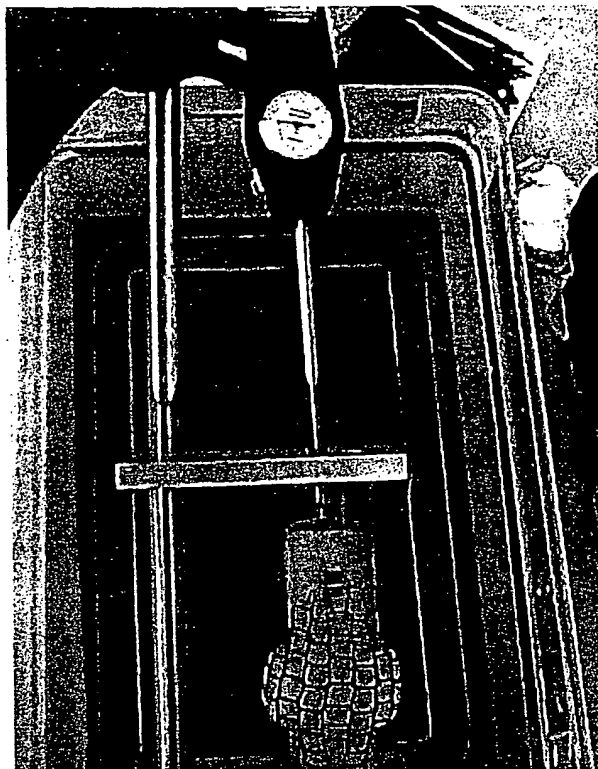


Figure 1: Tester using water in the bladder instead of air and submerged in water.

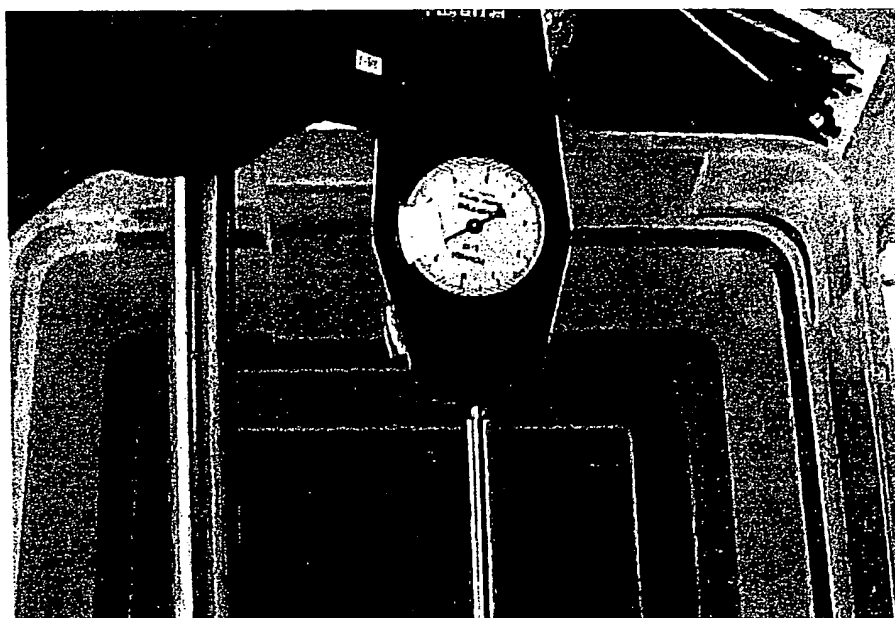


Figure 2: Ten pound force gauge attached to piston extender.

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PV/PD TESTER

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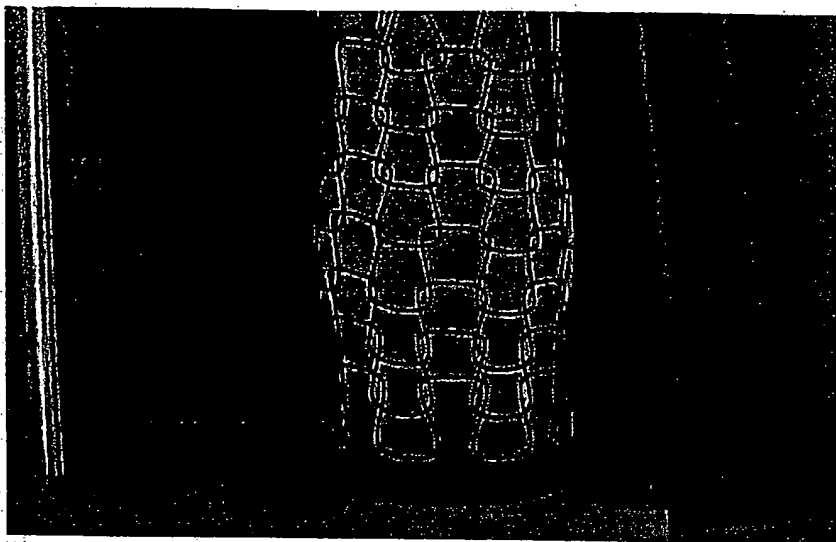


Figure 3: .015" harness with low pressure in bladder.

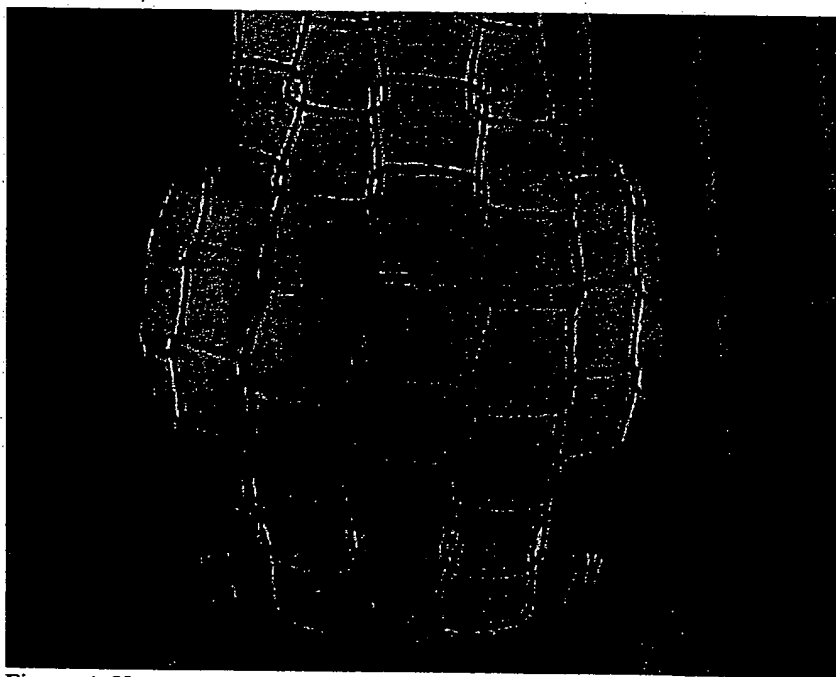


Figure 4: Harness extended, but restraining the bladder.

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